

BEFORE THE IOWA BOARD OF PHARMACY

Re:)
Pharmacy License of) Case No. 2012-52
BAUDER PHARMACY, INC.)
License No. 222) **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. On December 12, 2011, the Board renewed Respondent's general pharmacy license number 222 for Bauder Pharmacy (hereinafter, "Respondent"), 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. At all times material to this statement of charges, Respondent was operating as a general pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa, with Mark E. Graziano as the pharmacist in charge.

A. CHARGES

COUNT I

Respondent is charged under Iowa Code §§ 124.308(3), 124.402(1), 155A.15(2)(c), 155A.15(2)(h) (2011) and 657 Iowa Administrative Code § 36.1(4)(ac) with failing to maintain adequate control over and accountability for controlled substances.

COUNT II

Respondent is charged under Iowa Code § 155A.15(2)(c), 155A.15(2)(i) and 657 Iowa Administrative Code § 10.15 with inadequate security and failure to establish effective controls against diversion of controlled substances.

COUNT III

Respondent is charged under Iowa Code §§ 124.306, 155A.15(2)(c), 155A.15(2)(h) and 657 Iowa Administrative Code § 10.34 with failure to keep and maintain records as required by the Controlled Substances Act.

COUNT IV

Respondent is charged under Iowa Code § 155A.15(2)(h) and 657 Iowa Administrative Code § 8.9 with failure to properly sign and date invoices for controlled substances.

COUNT V

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.21 with dispensing Schedule II controlled substances in quantities exceeding prescriber authorization.

COUNT VI

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.23 with failure to comply with requirements for the partial filling of Schedule II controlled substances.

COUNT VII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.33 with failure to maintain complete and accurate perpetual inventories of Schedule II controlled substances.

COUNT VIII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.35 with failure to maintain a complete and accurate inventory of controlled substances.

COUNT IX

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 21.5 with failure to document verification of controlled substance refills.

COUNT X

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 3.20 with failure to properly supervise dispensing functions that are delegated to non-pharmacists.

COUNT XI

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.13 with failure to maintain complete patient records.

COUNT XII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code §§ 3.11 and 36.1(4)(aa) with failure to ensure that all pharmacy technicians have a current and active technician registration.

COUNT XIII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.2 with failure to maintain required policies and procedures for the operation of a pharmacy.

COUNT XIV

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.7 with failure to provide proper security for prescription medications and pharmacy records stored in the basement.

COUNT XV

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 8.14 with failure to have required policies, procedures and documentation for pharmacy technician training.

COUNT XVI

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 8.26 with failure to have a continuous quality improvement program.

COUNT XVII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code §§ 13.3, 13.6, 13.7, 13.11, 13.25, 13.27, 13.28, 13.29, and 13.31 with failure to meet minimum standards for sterile compounding.

COUNT XVIII

Respondent is charged under Iowa Code §§ 155A.15(2)(c) and 155A.15(2)(f) and 657 Iowa Administrative Code § 22.5 with failure to provide labeling and and record keeping for patient med paks.

COUNT XIX

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 36.1(4)(w) with failure to provide adequate patient counseling to patients.

B. CIRCUMSTANCES

An investigation was commenced on March 9, 2012, which revealed the following:

1. At all times material to this Statement of Charges, Respondent operated a general pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa 50312.
2. An audit of controlled substances handled by Bauder Pharmacy between January 1, 2008, and March 21, 2012, revealed a shortage of approximately 740,888 tablets of various strengths of hydrocodone APAP, a Schedule III controlled substance. This shortage was determined by obtaining information from the Automation of Reports and Consolidated Orders System (ARCOS) maintained by the U.S. Department of Justice, Drug Enforcement Administration. ARCOS is an automated, comprehensive drug reporting system which monitors the flow of certain DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level. Respondent acquired hydrocodone APAP products for Bauder Pharmacy from 14 different drug wholesalers between 2008 and 2012.
3. For the audit period of January 1, 2008 through March 21, 2012, ARCOS records indicate that Respondent ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of these hydrocodone APAP products were of one strength; hydrocodone APAP 7.5mg/500mg (593,700 tablets).
4. For the same audit period (January 1, 2008 through March 21, 2012), prescription monitoring program (PMP) records submitted by Respondent indicate that Respondent dispensed 358,012 hydrocodone APAP tablets (all brands, all strengths) to customers.
5. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets are not accounted for in Respondent's PMP dispensing records. Respondent has received, from wholesalers, 740,888 more tablets of hydrocodone APAP than Respondent has reported selling.
6. Shortages of hydrocodone APAP products at Bauder Pharmacy occurred as follows:
Calendar Year 2008: 229,846 tablets;
Calendar Year 2009: 163,185 tablets;
Calendar Year 2010: 155,436 tablets;
Calendar Year 2011: 182,732 tablets
January-March, 2012: 9,689 tablets.

7. Two shopper surveys in which prescriptions were filled at Bauder Pharmacy on March 8, 2012, and March 14, 2012, revealed numerous deficiencies including inadequate patient counseling, lack of patient privacy, failing to obtain required patient information, mislabeling of a prescription vial, and dispensing prescription medication in non-childproof prescription containers.
8. An inspection of Bauder Pharmacy on March 16, 2012, revealed the following additional deficiencies:
 - a) Technician Higgins' registration expired on September 30, 2010, and was not renewed in a timely manner.
 - b) Bauder Pharmacy has no pertinent policies and procedures as required by Board rules.
 - c) Security at Bauder Pharmacy for medications and records stored in the basement was found to be inadequate (second notice).
 - d) Respondent, Mark Graziano, was not wearing a badge which identified him as a pharmacist (second notice).
 - e) Bauder Pharmacy's controlled substance invoices were not signed and dated.
 - f) Bauder Pharmacy has no policy or documentation of technician training.
 - g) Bauder Pharmacy has no continuous quality improvement program
 - h) Bauder Pharmacy dispensed a Schedule II prescription in a quantity larger than what was authorized.
 - i) Bauder Pharmacy partially filled schedule II prescriptions past the 72 hour limitation.
 - j) Bauder Pharmacy's Schedule II perpetual inventory does not accurately reflect dispensing, resulting in negative balances.
 - k) Bauder Pharmacy's Schedule II invoices were not kept separate from Schedule III, IV and V invoices.
 - l) Bauder Pharmacy's annual controlled substance inventory was missing the quantity for hydrocodone APAP 2.5/500mg
 - m) Carisoprodol was not inventoried by Bauder Pharmacy when it became a Schedule IV controlled substance on January 11, 2012.
 - n) Bauder Pharmacy had no policies and procedures for sterile compounding.
 - o) Bauder Pharmacy had no quality assurance program for sterile compounding.
 - p) Bauder Pharmacy had no training documentation for personnel involved with sterile compounding.
 - q) Bauder Pharmacy had no batch records for sterile compounding and no labeling of product.
 - r) Bauder Pharmacy gave a longer expiration date to low risk compounded products than allowed.
 - s) Bauder Pharmacy has never conducted media fill testing.
 - t) Bauder Pharmacy's sterile compounding room has areas that need repair.
 - u) Bauder Pharmacy has no written cleaning procedures and no documentation of cleaning for sterile compounding areas.
 - v) The sterile compounding areas at Bauder Pharmacy have only been certified once a year instead of twice a year (second notice); microbial sampling has never been conducted; there were no pressure differential monitors; and there were no procedures concerning environmental requirements.

- w) Bauder Pharmacy had failed to document verification of controlled substance refills for the past two years.
- x) Bauder Pharmacy had no labeling or record keeping for patient med paks.
- y) Bauder Pharmacy has dispensed prescriptions in containers with non child-resistant packaging without proper authorization.
- z) Bauder Pharmacy has reused prescription vials.

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 3rd day of May 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: Theresa Weeg
 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 type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> Facsimile |
| Article Number _____ | <input type="checkbox"/> other _____ |

on the ____ day of May 2012.

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

 Jean Rhodes, Compliance Officer

BEFORE THE IOWA BOARD OF PHARMACY

Re:) Case No. 2012-52
Controlled Substance Registration of)
BAUDER PHARMACY, INC.) **ORDER OF IMMEDIATE**
Registration No. 1100280) **SUSPENSION**
Respondent.) **AND**
) **ORDER TO SHOW CAUSE**

TO: BAUDER PHARMACY INC.
3802 Ingersoll Ave
Des Moines, Iowa 50312

NOTICE: Pursuant to the provisions of Iowa Code § 124.305(2) (2011) and 657 Iowa Administrative Code § 10.12(9), controlled substance registration number 1100280, issued to Bauder Pharmacy, Inc., is hereby **IMMEDIATELY SUSPENDED.**

NOTICE: Pursuant to the provisions of Iowa Code § 124.305(1) (2011) and 657 Iowa Administrative Code § 10.12(5), you are hereby ordered to appear before the Iowa Board of Pharmacy and show cause why controlled substance registration number 1100280, issued to Bauder Pharmacy, Inc., should not be revoked. **IF YOU DESIRE A HEARING REGARDING SUSPENSION AND POSSIBLE 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 chapters 124 and 155A (2011), and 657 Iowa Administrative Code § 10.1, et seq., the Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over those who manufacture, distribute, and dispense controlled substances in Iowa. On June 6, 2011, the Board issued to Bauder Pharmacy Inc. (hereinafter, "Respondent"), subject to the laws of the State of Iowa and the rules of the Board, a renewal of controlled substance registration number 1100280. At all times material to these proceedings, Respondent was operating a retail pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa 50312.

II. BASIS FOR ORDER TO SHOW CAUSE

On or about March 5, 2012, the Board commenced an investigation of Respondent which revealed the following:

1. Respondent operates a retail pharmacy located at 3802 Ingersoll Avenue, Des Moines, Iowa. On June 6, 2011, the Board issued Respondent a renewal of controlled substance registration number 1100280.
2. An audit of controlled substance dispensing records, performed in connection with the March 5, 2012 investigation, revealed that substantially greater quantities of controlled substances have been ordered by Respondent from wholesalers than were reported by Respondent as sold to pharmacy customers. Prescription monitoring program (PMP) records and the federal Drug Enforcement Administration's "automation of reports and consolidated orders system" (ARCOS) records were reviewed. Comparison and analysis of the records revealed that Respondent has followed a practice of ordering from an unusually diverse number of drug wholesalers. From 2008-2012, fourteen wholesalers provided hydrocodone APAP to Respondent in three strengths: 10/325, 5/500 and 7.5/500. Hydrocodone APAP is a Schedule III controlled substance.
3. For the audit period of January 1, 2008 through March 21, 2012, ARCOS records indicate that Respondent ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of these hydrocodone products were of one strength; hydrocodone APAP 7.5/500 (593,700 tablets).
4. For the same audit period (January 1, 2008 through March 21, 2012), PMP records submitted by Respondent indicate that Respondent dispensed 358,012 Hydrocodone APAP tablets (all brands, all strengths) to customers.

5. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets are not accounted for in Respondent's PMP dispensing records. Respondent has received, from wholesalers, 740,888 more tablets of hydrocodone APAP than Respondent has reported selling.
6. Analyzed on an annual basis, Respondent's unaccounted for hydrocodone APAP tablets number as follows:
 - 2008 – 229,846 tablets
 - 2009 – 163,185 tablets
 - 2010 – 155,436 tablets
 - 2011 – 182,732 tablets
 - 2012 – 9,689 tablets
7. An audit of Respondent's PMP-reported Oxycodone sales – again utilizing a comparison of ARCOS records of controlled substance purchases with PMP records of controlled substance sales – revealed more Oxycodone product dispensing than would be possible with the supplies delivered by wholesalers. For the audit period January 1, 2008 through March 21, 2012, Respondent received 1,293 fewer Oxycodone tablets than Respondent reported selling. Additionally, Respondent's submissions to the PMP indicate Respondent was charging for brand name Oxycodone products (Endocet, Roxicet and Percocet) while dispensing generic Oxycodone products. During the audit period, Respondent's reports to the PMP indicate 5,269 tablets of Roxicet were reported dispensed. However, during the same period, only 1,500 tablets of Roxicet were shipped to Respondent by wholesalers.

III. BASIS FOR ORDER OF IMMEDIATE SUSPENSION

The Board finds as follows:

1. For the audit period January 1, 2008 through March 21, 2012, a total of 740,888 hydrocodone APAP tablets, shipped to Respondent by wholesalers, are not accounted for by Respondent's PMP records of prescription sales.
2. The void in Respondent's dispensing (PMP) records indicates that, for the audit period January 1, 2008 through March 21, 2012, approximately 740,888 hydrocodone APAP tablets were diverted or dispensed in violation of the provisions of Iowa Code chapters 124 and 155A (2011).
3. Hydrocodone APAP is an addictive Schedule III controlled substance, frequently distributed illegally. The Iowa legislature has determined that use of hydrocodone APAP may lead to moderate physical dependence and high psychological dependence. Iowa Code § 124.207 (2011).
4. Illegal distribution of large quantities of hydrocodone APAP represents a threat to the public health and safety due to the addictive nature of the drug. The assembled evidence indicates that Respondent has engaged in a steady, repeated practice of illegal hydrocodone APAP distribution over a period of more than four years. The amount of hydrocodone APAP not accounted for in Respondent's pharmacy records – 740,888 hydrocodone APAP tablets – is very large considering the moderate size of Respondent pharmacy and the emphasis the Board places on accurate record keeping and security of controlled substances. Approximately two thirds of the hydrocodone APAP being purchased by Respondent is not accounted for in the PMP records provided by Respondent. There is no likelihood that the substantial discrepancy between wholesaler shipping records and Respondent's dispensing records can be explained as a simple record-keeping error.

5. Records indicate that another controlled substance, Oxycodone – in generic form, is being sold to patients as name-brand products such as Endocet, Roxicet and Percocet.

IV. ORDER

1. Respondent's Controlled Substance Registration is IMMEDIATELY SUSPENDED UPON SERVICE.
2. Respondent is hereby ORDERED to immediately upon service return controlled substance certificate of registration, number 1100280, to the Board.
3. Respondent is hereby ORDERED to immediately deliver all controlled substances in the Respondent's possession to the Board or authorized agent of the Board.
4. Respondent is ORDERED to appear before the Iowa Board of Pharmacy and show cause why controlled substance registration number 1100280, issued in Respondent's name, should not be revoked. If Respondent wishes to have a hearing before the Board in response to this Order, Respondent must notify the Board 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. A hearing is tentatively set for 9:00 a.m., June 26, 2012, at the Board's offices, pending Respondent's request for a hearing.

IF RESPONDENT DOES NOT REQUEST HEARING IN THIS MATTER WITHIN THIRTY DAYS OF THE DATE OF THIS ORDER, RESPONDENT'S CONTROLLED SUBSTANCE REGISTRATION WILL BE DEEMED REVOKED WITHOUT FURTHER ORDER OF THE BOARD.

IT IS SO ORDERED THIS 3rd day of May 2012.



SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy

cc: Theresa Weeg, Assistant Iowa Attorney General
Drug Enforcement Administration, Des Moines

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 _____ | <input type="checkbox"/> other _____ |

on the ____ day of May 2012.

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

Jean Rhodes, Compliance Officer

BEFORE THE IOWA BOARD OF PHARMACY

Re:) Case Nos. 2012-52
Pharmacy License of)
BAUDER PHARMACY, INC.)
License No. 222,) **MOTION TO AMEND**
Respondent.) **STATEMENT OF CHARGES**

COMES NOW the State of Iowa and moves to amend the Statement of Charges in this matter, as set forth below, and in support states:

1. The State seeks to amend the pending charges to assert new factual allegations.
2. The hearing in this matter is scheduled for November 8, 2012.
3. The Iowa Supreme Court allowed a similar amendment to the statement of charges in the case of Rosen v. Board of Medical Examiners, 539 N.W.2d 345 (Iowa 1996). In that case the Supreme Court allowed a request for amendment to enlarge the factual basis supporting the charges, even though it was made in the course of the hearing itself.
4. It is in the interest of justice to allow this amendment. The new factual allegations concern Respondent's ability to ensure its pharmacy practice is safe, and therefore affect the public's health and welfare. There is sufficient time to prepare a defense to these new complaints. It would be unnecessary duplication of the time and resources of both parties and the Board to require the Board to initiate an entirely new proceeding in this matter.

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IOWA BOARD OF PHARMACY

5. A copy of the first amended charges proposed by the State is attached as Exhibit A. The substantive changes are the additions of Counts XX-XXVI and paragraphs 9-11 in the Circumstances.

WHEREFORE, the State of Iowa requests the Board amend the charges as set forth above.

Respectfully submitted,

THOMAS J. MILLER
ATTORNEY GENERAL OF IOWA



THERESA O'CONNELL WEEG
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor Hoover Bldg.
Des Moines, IA 50319
515.281.5328
tweeg@ag.state.ia.us

cc: Rick L. Olson
2635 Hubbell Ave.
Des Moines, IA 50317

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing instrument was served upon each of the attorneys of record of all parties in the above-entitled cause by enclosing the same in an envelope addressed to each such attorney at his respective address as disclosed by the pleadings of record herein, with postage fully paid, and by depositing said envelope in a United States Post Office depository in Des Moines, Iowa, on the 5th day of October, 2012.

R. Dale

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2012-52
BAUDER PHARMACY, INC.)	
License No. 222,)	FIRST AMENDED
Respondent.)	STATEMENT OF CHARGES
)	

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

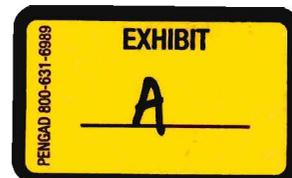
1. He is the Executive Director for the Iowa Board of Pharmacy (hereinafter, "Board") and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2011).
3. On December 12, 2011, the Board renewed Respondent's general pharmacy license number 222 for Bauder Pharmacy (hereinafter, "Respondent"), 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. On May 10, 2012, the Board filed a Statement of Charges against Respondent's general pharmacy license. On that same date, the Board filed an Order of Immediate Suspension and Order to Show Cause against Respondent, immediately suspending Respondent's Controlled Substance Registration. Because Respondent did not request a hearing within thirty days of this Order, Respondent's Controlled Substance Registration was deemed revoked.
5. At all times material to this statement of charges, Respondent was operating as a general pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa, with Mark E. Graziano as the pharmacist in charge.

A. CHARGES

COUNT I

Respondent is charged under Iowa Code §§ 124.308(3), 124.402(1), 155A.15(2)(c), 155A.15(2)(h) (2011) and 657 Iowa Administrative Code § 36.1(4)(ac) with failing to maintain adequate control over and accountability for controlled substances.

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Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.2 with failure to maintain required policies and procedures for the operation of a pharmacy.

COUNT XIV

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.7 with failure to provide proper security for prescription medications and pharmacy records stored in the basement.

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Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 8.14 with failure to have required policies, procedures and documentation for pharmacy technician training.

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COUNT XVII

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code §§ 13.3, 13.6, 13.7, 13.11, 13.25, 13.27, 13.28, 13.29, and 13.31 with failure to meet minimum standards for sterile compounding.

COUNT XVIII

Respondent is charged under Iowa Code §§ 155A.15(2)(c) and 155A.15(2)(f) and 657 Iowa Administrative Code § 22.5 with failure to provide labeling and record keeping for patient medications.

COUNT XIX

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 36.1(4)(w) with failure to provide adequate patient counseling to patients.

COUNT XX

Respondent is charged under Iowa Code §§ 155A.19(1)(d) and 155A.15(2)(c) and 657 Iowa Administrative Code § 8.35(6)(c) with failing to report to the Board a change in the pharmacist in charge and to comply with the requirements for making a change in the pharmacist in charge.

COUNT XXI

Respondent is charged under Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code § 8.19 for failing to comply with the rules of the Board regarding the manner of issuance of a prescription drug or medication order, and for the owner of the pharmacy and its employees failing to comply with these rules.

COUNT XXII

Respondent is charged under § 155A.15(2)(c) and 657 Iowa Administrative Code § 10.21 with failing to comply with the rules of the Board regarding prescription requirements.

COUNT XXIII

Respondent is charged under § 155A.15(2)(c) and 657 Iowa Administrative Code §§ 21.9 and 21.3 with failing to comply with the rules of the Board regarding faxed prescriptions.

COUNT XXIV

Respondent is charged under § 155A.15(2)(c) and 657 Iowa Administrative Code § 6.8 with failing to comply with the rules of the Board regarding prescription processing documentation.

COUNT XXV

Respondent is charged under §§ 155A.15(2)(c) and 155A.15(2)(h), and 657 Iowa Administrative Code § 8.9, with failing to comply with the rules of the Board regarding record retention requirements.

COUNT XXVI

Respondent is charged under § 155A.15(2)(c) and 124.308(4) with dispensing controlled substances without a prescription.

B. CIRCUMSTANCES

An investigation was commenced on March 9, 2012, which revealed the following:

1. At all times material to this Statement of Charges, Respondent operated a general pharmacy at 3802 Ingersoll Avenue, Des Moines, Iowa 50312.
2. An audit of controlled substances handled by Bauder Pharmacy between January 1, 2008, and March 21, 2012, revealed a shortage of approximately 740,888 tablets of various strengths of hydrocodone APAP, a Schedule III controlled substance. This shortage was determined by obtaining information from the Automation of Reports and Consolidated Orders System (ARCOS) maintained by the U.S. Department of Justice, Drug Enforcement Administration. ARCOS is an automated, comprehensive drug reporting system which monitors the flow of certain DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level. Respondent acquired hydrocodone APAP products for Bauder Pharmacy from 14 different drug wholesalers between 2008 and 2012.
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Calendar Year 2010: 155,436 tablets;
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8. An inspection of Bauder Pharmacy on March 16, 2012, revealed the following additional deficiencies:
 - a) Technician Higgins' registration expired on September 30, 2010, and was not renewed in a timely manner.
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 - c) Security at Bauder Pharmacy for medications and records stored in the basement was found to be inadequate (second notice).
 - d) Respondent, Mark Graziano, was not wearing a badge which identified him as a pharmacist (second notice).
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 - f) Bauder Pharmacy has no policy or documentation of technician training.
 - g) Bauder Pharmacy has no continuous quality improvement program
 - h) Bauder Pharmacy dispensed a Schedule II prescription in a quantity larger than what was authorized.
 - i) Bauder Pharmacy partially filled schedule II prescriptions past the 72 hour limitation.
 - j) Bauder Pharmacy's Schedule II perpetual inventory does not accurately reflect dispensing, resulting in negative balances.
 - k) Bauder Pharmacy's Schedule II invoices were not kept separate from Schedule III, IV and V invoices.
 - l) Bauder Pharmacy's annual controlled substance inventory was missing the quantity for hydrocodone APAP 2.5/500mg
 - m) Carisoprodol was not inventoried by Bauder Pharmacy when it became a Schedule IV controlled substance on January 11, 2012.
 - n) Bauder Pharmacy had no policies and procedures for sterile compounding.
 - o) Bauder Pharmacy had no quality assurance program for sterile compounding.
 - p) Bauder Pharmacy had no training documentation for personnel involved with sterile compounding.
 - q) Bauder Pharmacy had no batch records for sterile compounding and no labeling of product.
 - r) Bauder Pharmacy gave a longer expiration date to low risk compounded products than allowed.
 - s) Bauder Pharmacy has never conducted media fill testing.
 - t) Bauder Pharmacy's sterile compounding room has areas that need repair.
 - u) Bauder Pharmacy has no written cleaning procedures and no documentation of cleaning for sterile compounding areas.
 - v) The sterile compounding areas at Bauder Pharmacy have only been certified once a year instead of twice a year (second notice); microbial sampling has never been conducted;

there were no pressure differential monitors; and there were no procedures concerning environmental requirements.

- w) Bauder Pharmacy had failed to document verification of controlled substance refills for the past two years.
 - x) Bauder Pharmacy had no labeling or record keeping for patient med paks.
 - y) Bauder Pharmacy has dispensed prescriptions in containers with non child-resistant packaging without proper authorization.
 - z) Bauder Pharmacy has reused prescription vials.
9. After the Statement of Charges and Order of Immediate Suspension and Order to Show Cause were filed against Respondent, a second audit was performed utilizing wholesaler invoices and Respondent's computerized drug usage reports to verify previous audit results. The date range of the audits was January 1, 2008, through March 21, 2012. One wholesaler was unable to provide data for the period prior to November 4, 2009.
- a) For this audit period, a total of 689,987 Hydrocodone APAP tablets are not accounted for in Respondent's records. Respondent has received, from wholesalers, 689,987 more Hydrocodone APAP tablets than Respondent has reported selling.
 - b) In 2010-2011, a pharmacist working for Respondent signed invoices for the purchase of 98,519 more tablets of Hydrocodone APAP 7.5-500mg than Respondent's records show were dispensed.
 - c) Based on information obtained from wholesalers, from 2010-2012 Respondent is missing 137 invoices, totalling 144,000 doses of Hydrocodone APAP 7.5-500mg.
 - d) Respondent is missing numerous annual inventories of Hydrocodone products.
 - e) Following this audit, shortages of hydrocodone APAP products at Bauder Pharmacy were verified as follows:

Calendar Year 2008: 200,936 tablets
Calendar Year 2009: 130,265 tablets
Calendar Year 2010: 157,524 tablets
Calendar Year 2011: 181,263 tablets
January-March, 2012: 19,999 tablets

10. After the Statement of Charges and Order of Immediate Suspension and Order to Show Cause were filed against Respondent, the Board received additional information about diversion at Respondent's pharmacy. That information indicated that on several occasions prior to May 10, 2012, Respondent's Pharmacist in Charge was observed to have personally handed Hydrocodone APAP 7.5-500mg to another person out of the pharmacy's back door.
11. After the Statement of Charges and Order of Immediate Suspension and Order to Show Cause were filed against Respondent, the following deficiencies were identified:
- a) Respondent failed to identify a new Pharmacist in Charge for over two months after the license of its prior Pharmacist in Charge was suspended on May 10, 2012.

b) A Board review of 612 randomly-selected prescriptions from 2008-2012 revealed that only 166 fulfilled the legal requirements of a prescription. The deficiencies included:

- i) Wrong patient
- ii) Wrong prescriber
- iii) Wrong medication
- iv) No prescriber signature or verification
- v) Wrong number of refills
- vi) Wrong directions
- vii) No prescriber DEA number for controlled substances
- viii) Faxed prescription not signed by prescriber
- ix) Wrong dispensed quantity
- x) Prescription filled beyond authorized time period
- xi) Prescription filled prior to authorization
- xii) Prescription denied by prescriber but filled by pharmacy
- xiii) No prescribed quantity
- xiv) Prescription number not recorded on prescription
- xv) Generic was dispensed when prescription indicated "do not substitute"
- xvi) Sender's information cut off from fax

c) A review of 95 prescriptions for Androgel (testosterone), a Schedule III controlled substance, revealed only 3 fulfilled the legal requirements of a prescription. The deficiencies included:

- i) No prescriber DEA number\
- ii) No hardcopy in the file
- iii) No prescriber signature
- iv) Stamped prescriber signature
- v) Unauthorized refills dispensed
- vi) Prescription refilled beyond 6 months
- vii) Prescription initially filled after prescription had expired
- viii) No patient name on hard copy of prescription
- ix) No notation of verbal authorization
- x) No prescription number on prescription
- xi) Sender information cut off from fax
- xii) Wrong dosage form of medication
- xiii) Prescription filled prior to receipt of fax authorization

d) Androgel prescriptions of three patients were reviewed with their prescribers. Of the 22 prescriptions, only 11 were identified as authorized, resulting in Respondent dispensing 1200 unauthorized doses of a controlled substance.

e) The controlled substance dispensing history of one patient was reviewed with the patient's prescriber. Only two of the seven prescriptions for Lortab (Hydrocodone and Acetaminophen 7.5/500mg), a schedule III controlled substance, were authorized,

resulting in Respondent dispensing 820 unauthorized doses of a controlled substance in a one year period.

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 ____ day of _____, 2012, the Iowa Board of Pharmacy found probable cause to file this First Amended Statement of Charges.

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
Hoover State Office Building
Des Moines, Iowa

Rick L. Olson
2635 Hubbell Ave.
Des Moines, IA 50317

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF :

BAUDER PHARMACY, INC.)	CASE NO. 2012-52
License No. 222, and)	
)	RULING GRANTING STATE'S
MARK GRAZIANO)	MOTION TO AMEND
Pharmacist License No. 16752)	STATEMENT OF CHARGES
RESPONDENTS)	

On May 3, 2012, the Iowa Board of Pharmacy (Board) found probable cause to file Statements of Charges against Bauder Pharmacy, Inc. and Mark Graziano (Respondents). In addition, the Board issued an Order of Immediate Suspension of the controlled substances registration number 1100280 issued to Bauder Pharmacy Inc. The Board also issued an Emergency Order indefinitely suspending the pharmacist license of Mark Graziano.

On October 8, 2012, the state of Iowa filed Motions to Amend the Statements of Charges against both Respondents to add additional legal counts and additional factual circumstances. The new counts and new circumstances were based on a second audit performed after the initial Statements of Charges were filed. Both Motions to Amend included a copy of the proposed First Amended Statement of Charges.

Respondents have not filed any resistance to the Amended Statements of Charges.

The Board has delegated ruling on the Motions to Amend to the undersigned administrative law judge. The hearing has now been continued to February 26, 2013. Respondents have been afforded sufficient opportunity to prepare a defense to the additional charges. It is in the interest of judicial economy for the Board to hear and determine all pending charges in one disciplinary proceeding. IT IS THEREFORE ORDERED that the State's Motions to Amend the Statements of Charges filed against Respondents Bauder Pharmacy, Inc. and Mark Graziano are hereby GRANTED.

RECEIVED

DEC 03 2012

IOWA BOARD OF PHARMACY

Dated this 30th day of November, 2012.

Margaret LaMarche

Margaret LaMarche
Administrative Law Judge
Iowa Department of Inspections and Appeals
Division of Administrative Hearings
Wallace State Office Building-Third Floor
Des Moines, Iowa 50319
[For the Iowa Board of Pharmacy]

cc: Rick Olson, 2635 Hubbell Ave., Des Moines, IA 50317 (CERTIFIED)
Theresa O'Connell Weeg, Department of Justice, Hoover Bldg, 2nd Fl.
(LOCAL)
Lloyd Jessen and Debbie Jorgenson, Iowa Board of Pharmacy, 400 SW 8th
Street, Suite C, Des Moines (LOCAL)

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:)	CASE NO: 2012-52
)	DIA NOS. 12PHB029
Pharmacy License of)	
BAUDER PHARMACY, INC.)	
License No. 222)	
)	FINDINGS OF FACT,
Pharmacist License of)	CONCLUSIONS OF LAW,
MARK GRAZIANO)	DECISION AND ORDER
License No. 16752)	
)	
RESPONDENTS)	

On May 3, 2012, the Iowa Board of Pharmacy (Board):

- found probable cause to file Statements of Charges against Bauder Pharmacy, Inc. and Mark Graziano (Respondents);
- issued an Order of Immediate Suspension and Order to Show Cause that immediately suspended the controlled substances registration (number 1100280) issued to Bauder Pharmacy Inc.; and
- issued an Emergency Adjudicative Order indefinitely suspending the pharmacist license of Mark Graziano.

These documents were personally served on Respondents Bauder Pharmacy, Inc. and Mark Graziano on May 10, 2012. A June 26, 2012 hearing was initially scheduled on the Emergency Adjudicative Order and Statement of Charges issued to Mark Graziano. The hearing was continued four times at Respondents' request.

On October 8, 2012, the state filed Motions to Amend the Statements of Charges and First Amended Statements of Charges against both Respondents. Respondents did resist the Motions to Amend the Statements of Charges, and the motions were granted on November 30, 2012. Prehearing conferences were held on January 30 and February 22, 2013.

The consolidated hearing was held on February 26 and 27, 2013 in the Board Conference Room, 400 SW 8th Street, Des Moines, Iowa. The following members

of the Board served as presiding officers for the hearing: DeeAnn Wedemeyer Oleson, Vice-Chairperson; James Miller; Edward McKenna; and LaDonna Gratias. Assistant Attorney General Theresa O'Connell Weeg represented the state. Respondents Bauder Pharmacy and Mark Graziano were represented by attorney Rick Olson. The hearing was open to the public at Respondents' request, in accordance with Iowa Code section 272C.6(1) and 657 IAC 35.19(10). Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was later instructed to prepare the Board's written Decision and Order, in conformance with their deliberations.

THE RECORD

The hearing record includes the testimony of Jean Rhodes, Sue Mears, Kirby Small, Lloyd Jessen, Jennifer Higgins, and Mark Graziano. The record also includes State Exhibits 1-77 and 79 and Respondent Exhibits D-N. A Protective Order was issued for all exhibits containing patient names, with the exceptions of Respondents' Exhibits L and M. The record also includes the following procedural motions and orders: Board Orders Granting Motions to Continue; Order Following Prehearing Conference; State and Respondent Witness and Exhibits Lists; State Motion to Strike Lloyd Jessen from Respondent's Witness List, Respondent Resistance, and Order Denying State's Request to Strike; Respondent's Objections to State Exhibits and Order Overruling Respondent's Objections; State Motion for Protective Order and Order Granting Protective Order; and State's Hearing Brief.

FINDINGS OF FACT

Licensure/Ownership/Staffing of Bauder Pharmacy

1. At all times material to this Decision and Order, Bauder Pharmacy, Inc. operated a licensed general pharmacy (license number 222) located at 3802 Ingersoll Avenue in Des Moines, Iowa. At all times material to this Decision and Order, Mark Graziano, R.Ph. was both the majority owner and the pharmacist in charge of Bauder Pharmacy. Mr. Graziano has been licensed to practice pharmacy (license number 16752) in the state of Iowa since 1986. (Jean Rhodes testimony; State Exhibits 1, 3, 5, 7)
2. Bauder Pharmacy is a small, independently owned retail pharmacy that also has a lunch counter and soda fountain. Mark Graziano owns 68% of Bauder

Pharmacy; his sister, Kim Robertson, owns 20%; and his mother owns the remaining 12%. Kim Robertson is also an Iowa licensed pharmacist and was working full-time at Bauder Pharmacy at all times relevant to the Statements of Charges. Bauder Pharmacy also had the following employees:

- Jay Wangerin, R.Ph., who was working as a part-time pharmacist (approximately 12 hours a week);
- Jennifer Higgins, who was working as a full-time pharmacy technician (45 hours a week);
- Jolene Cavanaugh, who worked at the lunch counter, ordered over-the-counter products for the store, and handled customer billing; and
- Shannon McGuire, who worked in the soda fountain.

(Rhodes, Graziano, Higgins testimony; State Exhibits 11, 29-34)

Anonymous Complaint Re: Illegal Distribution of Hydrocodone

3. On September 28, 2011, the Board received an anonymous telephone complaint from a person who claimed that Mark Graziano was illegally distributing 5,000 to 10,000 hydrocodone pills a month from Bauder Pharmacy. According to the anonymous complainant, Mark Graziano handed the hydrocodone bottles out the back door of the pharmacy to an individual who distributed them. The complainant stated that he was willing to submit a complaint form but hoped to remain anonymous because Mark Graziano had threatened him with “guys from out of state” if he spilled the beans. The complainant also claimed that Mark Graziano had him hooked on hydrocodone, but that he was now trying to get clean. (State Exhibit 8) The Board did not hear from the complainant again until May 11, 2012. (State Exhibit 35)

Shopper Surveys of Bauder Pharmacy

4. In March 2012, inspectors from the National Association of Boards of Pharmacy conducted two “shopper surveys” at Bauder Pharmacy. Both inspectors presented themselves to the pharmacy as new customers with new prescriptions. Both inspectors completed an Iowa Pharmacy Shopper Survey Reporting Form that describe a number of deficiencies in their “shopper” experience. (Rhodes testimony; State Exhibits 7, 9, 10)

a. There were two pharmacists on duty during the March 8, 2012 shopper survey conducted by inspector Cheryl Anderson, R.Ph. Ms. Anderson only had contact with one of the pharmacists, who she was later able to identify as Mark Graziano. Ms. Anderson initially gave her prescription to a female employee who was not wearing a name tag. The employee did not ask Ms. Anderson for any of her health history, current health conditions, medications, or allergies. Mr. Graziano asked Anderson for her date of birth and address. In her report, Ms. Anderson notes that Mr. Graziano appeared more focused on a man who had entered the pharmacy while her prescription was being filled. The man did not stop at the drop-off or pick-up counter but walked directly to the rear of the pharmacy.

Ms. Anderson's prescription was ready in less than 10 minutes. The female employee took Anderson's payment and asked Mr. Graziano if Anderson needed to know anything. Mr. Graziano told the employee "take in AM." When the employee looked puzzled, Mr. Graziano said "Cheryl, take in AM" and then walked to the rear of the pharmacy. Ms. Anderson was not provided any counseling literature or monograph with the prescription. Mr. Graziano did not counsel Ms. Anderson on any of the medication's possible side effects, which included increased urination, decrease in blood pressure, and dizziness. The prescription given to Anderson was mislabeled. The label read: "Triamterene-HCTZ 37.5-2#15, but the drug strength for the HCTZ was 25 mg not 2 mg. In addition, the prescription bottle had an easy open lid that was not requested or authorized by Ms. Anderson. (State Exhibit 9)

b. A female in a white lab coat waited on secret shopper Denise Frank at the time of the March 14, 2012 survey. The female employee was not wearing a name tag and did not identify herself to Ms. Frank as a pharmacist. The employee asked Ms. Frank about allergies but did not ask about her disease states or any other medications that she was taking. Ms. Frank noted in her report that it would have been prudent of the pharmacist to ask her about her OTC medications in order to prevent duplicate therapy because the prescription medication was also available over-the-counter.

Ms. Frank also noted that there were no privacy panels for the counseling area. A customer was standing directly behind her while the female waited on her and customers at the fountain counter could hear everything being said. The prescription was ready in eight minutes, and the female employee spoke to Ms. Frank as she rang up the order. The employee told Frank to avoid caffeine and

spicy foods and added "it's 1 twice a day." The prescription was put in a non-child proof container that Ms. Frank did not request. (State Exhibit 10)

March 16, 2012 Pharmacy Inspection

5. Jean Rhodes, R.Ph. has been a pharmacist for 14 years and has been employed by the Board as a Compliance Officer for 8½ years. On March 16, 2012, Ms. Rhodes was assigned to conduct a pharmacy inspection of Bauder Pharmacy and to prepare an inspection report. This inspection was prompted by the anonymous complaint and by the results of the shopper surveys. Ms. Rhodes was assisted by Sue Mears, R.Ph., who was a new compliance officer in training. (Rhodes, Mears testimony)

Bauder Pharmacy's last inspection had been conducted on July 24, 2008.¹ Ms. Rhodes explained the time gap between the two inspections. There is a backlog of routine pharmacy inspections, and the four year gap between inspections at Bauder Pharmacy is not that unusual. Some pharmacies have not had an inspection in 5 or 6 years. The Board's Compliance Officers are assigned to specific territories, and they give first priority to complaint investigations. If there is a need for a complaint investigation, the Compliance Officer will usually conduct a routine inspection at the same time. (Rhodes testimony; State Exhibits 7, 11; Respondent Exhibit N)

a. The Pharmacy Inspection Report was issued by Jean Rhodes on March 22, 2012. The report notes that Bauder Pharmacy maintains the following hours: Monday-Friday 8:30-6:00, Saturdays 9:00-3:00, Sundays 10:00-12:00, and Holidays, 10:00-12:00. The retail store and lunch counter are only open when the pharmacy is also open because the pharmacy dispensing area cannot be separately locked. At the time of the March 16th inspection, the pharmacy was performing sterile compounding of two medications (Lupron and HCG). The counseling area was limited. The pharmacy specialized in fertility medications, and fertility counseling was encouraged before and after business hours to promote confidentiality. (State Exhibit 11, pp. 57-58)²

¹ The July 2008 inspection included an audit of Schedule II controlled substances but did not include an audit of Schedule III or IV controlled substances. The inspection report only included a count of the Schedule III and IV inventory on hand. A total of 3000 tablets of all dosages of hydrocodone APAP were on hand in the pharmacy at the time of the 2008 audit. (Respondent Exhibit N)

² The page numbers provided in the Decision and Order refer to the consecutive pagination throughout the state's exhibit book which is found in the lower right hand corner of each page.

b. During the March 16th inspection, the Board's Compliance Officers reviewed the pharmacy's Schedule II Controlled Substance Perpetual Inventory, its annual inventory (last performed May 3, 2011), and hard-copies of prescriptions, invoices, and executed DEA 222 forms. The Compliance Officers did not perform a controlled substances audit during the March 16th inspection. (State Exhibit 11, pp. 57-58)

c. The Inspection Report describes the following areas of non-compliance requiring correction:

- **Registration renewal.** Pharmacy technician Jennifer Higgins' registration had expired on September 30, 2010 and had not been renewed. See 657 IAC 3.11(2). Ms. Higgins submitted her renewal application to the Board on March 20, 2012.
- **Pharmacist in charge.** The pharmacy had minimal policies and procedures, which are the responsibility of the pharmacist in charge. See 657 IAC 6.2(14). The Compliance Officers provided pharmacist Kim Robertson with a guideline handout for policies and procedures.
- **Security.** Outdated medications, including controlled substances, and patient records were not effectively secured against theft, diversion or unauthorized access. See 657 IAC 6.7, 657 IAC chapter 21. Outdated medications and patient records were stored in the basement, which could be accessed by any store personnel or by delivery drivers because the back door is adjacent to the basement stairs. This was the second notice concerning the pharmacy's storage of outdated drugs, and Mark Graziano was told to contact his reverse distributor for disposal of the drugs.
- **Identification badge.** Although visible name badges are required for pharmacists by Board rule, Pharmacist Mark Graziano admitted that he seldom wears a name badge because his customers all know him. This was the second notice on this violation. See 657 IAC 8.4(4).
- **Drug supplier invoices.** The pharmacy's controlled substance invoices needed to be signed and dated when received by the pharmacist or other responsible individual. 657 IAC 6.9(1).
- **Training and utilization of pharmacy technicians and pharmacy support.** The pharmacy did not have a written policy for training of pharmacy technicians and pharmacy support persons and did not document training. See 657 IAC 8.14.

- ***Continuous quality improvement program(CQI).*** The pharmacy did not have the required written CQI program, which is required to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate and prevent medication errors. Pharmacists Mark Graziano and Kim Robertson were able to explain their processes for a dispensing error. Mr. Graziano estimated that the pharmacy had about one error a week, while Ms. Robertson thought errors rarely happened. See 657 IAC 8.26.
- ***Schedule II prescriptions.*** RX 673021 was written for Oxy 20mg/ml, 10 ml, but the manufacturer supplies a 30ml container. The pharmacy had dispensed a 30ml container without documenting that the pharmacist contacted the prescriber for authorization to change the prescribed quantity. See 657 IAC 10.21(5).
- ***Schedule II prescriptions-partial filling.*** If the pharmacist is unable to supply the full quantity of Schedule II controlled substance prescription, the pharmacist may partially fill the prescription and make a notation on the record as long as the remaining portion of the prescription is filled within 72 hours. If the remaining portion of the prescription can't be filled within the 72 hours then the prescriber must be notified and a new prescription must be obtained. The pharmacy was partially filling Schedule II prescriptions and supplying the balance of the prescription beyond the 72 hour limit, resulting in several negative balances on the Schedule II perpetual log. See 657 IAC 10.23.
- ***Information included.*** The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug or by national drug code number. The record shall be updated to identify each prescription filled and each shipment received. The pharmacy had multiple negative balances in the Schedule II perpetual inventory. See 657 IAC 10.33(2).
- ***Schedule I and II records.*** Inventories and records of controlled substances listed on Schedule I and II must be maintained separately from all other records. The pharmacy kept its Schedule II invoices with its Schedule III-V invoices. See 657 IAC 10.34(1).
- ***Ordering or distributing Schedule I or II controlled substances-electronic ordering system.*** When a pharmacy receives a shipment of Schedule I or II drugs, it is required to create a record of the quantity of each item and the date received and then electronically link it to the original order and identify the individual reconciling the order. The pharmacy had never electronically linked the receipt of Schedule I and II drugs for a

wholesaler. During the inspection, Mr. Graziano called the wholesaler's help line and was instructed on the procedure. See 657 IAC 10.34(7).

- **Record and procedure.** Each inventory shall contain a complete and accurate record of all controlled substances on hand at the date and time inventory is taken. The pharmacy's annual inventory on 5/3/11 had no value for hydrocodone/APAP 2.5/500mg. If there is no drug, the entry should have been zero. Pharmacist Robertson believed they had copied the drug list from the previous year but had no 2.5/500 mg on hand as it is seldom used. See 657 IAC 10.35(1).
- **Newly controlled substances.** Carisoprodol became a Schedule IV drug on 1/12/12 but had not been inventoried as required by Board rule. See 657 IAC 10.35(8).
- **Sterile compounding.** Mark Graziano was the only pharmacist who prepared sterile compounded products. The following deficiencies were noted with respect to sterile compounding:
 - ✓ The pharmacy had a hood that was inspected yearly rather than every 6 months as required;
 - ✓ The pharmacy lacked a written quality assurance (QA) procedure and lacked written policies and procedures for sterile compounding. 657 IAC 13.3(2), 13.6, 13.31;
 - ✓ The pharmacy lacked documentation of the training and proficiency of its personnel involved with sterile compounding. 657 IAC 13.3(3);
 - ✓ The refrigerator had two unlabeled vials of HCG injectable. There were no batch records and no labeling of the product. 657 IAC 13.7(2);
 - ✓ Lupron injections were assigned a 30 day beyond-use date but are only permitted to have a 14 day beyond use date. 657 IAC 13.7(11);
 - ✓ Media fill testing was required annually but had never been done. 657 IAC 13.25;
 - ✓ There was peeling paint and areas that needed caulking in the buffer area where the primary engineering control device was located. 657 IAC 13.27(2);
 - ✓ There was no written cleaning procedures and no documentation of cleaning. 657 IAC 13.28;
 - ✓ All cleanrooms, laminar airflow workbenches, and barrier isolators are required to be certified every six months or whenever the device or room is relocated or altered or whenever major service to the facility is performed. Certification had only been done annually. 657 IAC 13.29.

- ✓ Microbial sampling had never been done, there were no pressure differential monitors, and there were no procedures concerning environmental requirements. 657 IAC 13.29.
- **Verification of controlled substance refills.** The pharmacy had not verified controlled substance refills through a daily printout or logbook for the prior two years. Mark Graziano mistakenly believed that the Patient Monitoring Program (PMP) fulfilled this requirement. 657 IAC 21.25.
- **Patient med paks.** The pharmacy was preparing med paks for four customers with no labeling or recordkeeping for the med paks. Pharmacist Kim Robertson stated that she planned to discontinue providing med paks. 657 IAC 22.5.
- **Poison Prevention Packaging Act of 1970(PPPA), 15 U.S.C. §§ 1471-1476.** This Act requires pharmacies to dispense oral prescription drugs in special packaging unless the drug is exempt or the patient or prescribing practitioner requests nonspecial packaging. The majority of prescriptions were filled at Bauder Pharmacy using snap caps/easy off caps without documentation that the customer requested them. Pharmacist Robertson planned to contact customers to obtain signatures from those who want easy off caps. In addition, some of the pharmacy's customers brought in empty prescription vials for re-use, which also violates PPPA. Pharmacist Robertson agreed to stop this practice.

Bauder Pharmacy was required to correct these deficiencies and acknowledge the corrections to the Compliance Officer within 30 days of receipt of the inspection report. (Rhodes testimony; State Exhibit 11)

6. On April 12, 2012, Jean Rhodes met with Mark Graziano at the Board office to review Bauder Pharmacy's deficiency corrections. Although this type of review is usually conducted at the pharmacy, Mr. Graziano specifically asked to meet Ms. Rhodes at the Board's office. Ms. Rhodes made handwritten notes of their discussion on a copy of the inspection report (State Exhibit 71). Addendum #4 to Rhodes inspection report (State Exhibit 70) includes check marks for those items that Mark Graziano reported as corrected.

Ms. Rhodes notes from the meeting indicate, in part, that: the pharmacy technician's registration had been renewed, the unsecured outdated medications had been sent to a reverse distributor, someone was coming to destroy unsecured records stored in the basement, the pharmacist was wearing a name badge, the

controlled substances invoices had been signed and dated, there was a technician training policy and documentation of training, Schedule II invoices had been separated from Schedule III-V invoices, verification of control substance refills had been documented, and the pharmacy had started a signature log for dispensing medications in non-child proof containers. (Rhodes testimony; State Exhibits 70-71)

Only a few of the deficiencies in the sterile compounding area were reported as corrected. Media fill testing, microbial sampling, and pressure differential monitors were expected to be addressed in May. There were still no policies and procedures for sterile compounding. (Rhodes testimony; State Exhibits 70-71)

At hearing, Jean Rhodes explained the critical importance of the sterile compounding regulations to public health and safety. A company in Massachusetts had recently been cited for significant violations of sterile compounding regulations that resulted in patient illnesses and deaths. The Board's sterile compounding regulations provide a means to verify that pharmacies have a safe sterile compounding environment and to ensure that there are no microbes in the air that could contaminate the compounded product and potentially cause patient infection or death. In addition, pharmacies must also document that they have established proper policies, procedures, and training specific to sterile compounding. (Rhodes testimony)

Audit of ARCOS and PMP Records from 1/1/08-3/21/12 [First Audit]

7. Following the March 16th inspection, Compliance Officers Jean Rhodes and Sue Mears decided to audit the hydrocodone and oxycodone³ medications purchased and dispensed by Bauder Pharmacy from January 1, 2008 through March 21, 2012. For this audit, Rhodes and Mears reviewed records of drug orders maintained on the federal Automation of Reports and Consolidated Order System (ARCOS) and dispensing records maintained on the state Prescription Monitoring Program (PMP). (Rhodes testimony; State Exhibit 7, pp. 46, 49-50; State Exhibits 12-27)

- ARCOS is a database collected by the U.S. Department of Justice Drug Enforcement Administration (DEA), Office of Diversion Control. Drug manufacturers and wholesalers are required to report all orders of

³ Hydrocodone is a narcotic that is a Schedule III controlled substance. Oxycodone is a Schedule II controlled substance. (Rhodes testimony; See Iowa Code sections 124.206, 124.208)

Schedule I and Schedule II controlled substances and all narcotic controlled substances in Schedule III to ARCOS. Manufacturers and wholesalers report the ordering pharmacy's DEA number, a transaction date, and the trade name, drug code, quantity, dosage unit, dosage form, and national drug code for each drug that is ordered. (Rhodes, Jessen testimony; State Exhibits 18, 19)

- The Prescription Monitoring Program (PMP) was created by the Iowa legislature in 2009 to establish a central database of controlled substance prescriptions dispensed to patients in Iowa. At least twice a month, pharmacies must report all dispensing of Schedule II, III, and IV controlled substances to the PMP. The information reported must include the pharmacy's DEA number, the date that the prescription was filled, the prescription number, if the prescription is new or a refill, the NDC number for the drug, the quantity of the drug, the number of days of drug therapy provided by the drug as dispensed, patient information, the prescriber DEA number, the date the prescription was issued by the prescriber, and method of payment. (Rhodes testimony; See Iowa Code chapter 124.551-124.558; 657 IAC Chapter 37)

8. The results of the first audit are summarized in State's Exhibits 7 and 12. This audit revealed that for the period from January 1, 2008 to March 12, 2012:

- ARCOS records indicate that Bauder Pharmacy ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of the hydrocodone products were one strength, hydrocodone APAP 7.5/500 (593,700 tablets);
- PMP records indicate that Bauder Pharmacy dispensed 358,012 hydrocodone APAP tablets (all brands, all strengths) to customers;
- A total of 740,888 hydrocodone APAP tablets that were ordered from wholesalers could not be accounted for through Bauder Pharmacy's PMP dispensing reports. The vast majority of the unaccounted for hydrocodone products (530,336) were hydrocodone APAP 7.5mg/500mg.

The audit also broke down the number of unaccounted for hydrocodone APAP tablets by calendar year, as follows:

- Calendar Year 2008: 229,846 tablets;
- Calendar Year 2009: 163,185 tablets;

- Calendar Year 2010: 155,436 tablets;
- Calendar Year 2011: 182,732 tablets;
- January-March 2012: 9,689 tablets

The compliance officers also created spreadsheets and graphs showing monthly totals for all hydrocodone and all oxycodone products, as well as breakdown totals for each type of product. Jean Rhodes spoke to DEA agent William Siegert who estimated that the higher strength tablets of hydrocodone (7.5mg and 10mg) had a street value ranging from \$10-\$20 a pill. (Rhodes testimony; State Exhibits 7, 12-27)

9. During the March 16, 2012 inspection of Bauder Pharmacy, pharmacist in charge Mark Graziano told Jean Rhodes that Bauder Pharmacy used the following 4 wholesalers: Anda, McKesson, H.D.Smith, and Dakota Drug. Mr. Graziano told Rhodes that he used four suppliers because of drug shortages. (Rhodes testimony; State Exhibit 7, p. 49)

When reviewing the ARCOS records for Bauder Pharmacy, however, the compliance officers observed that Bauder Pharmacy had used 14 different wholesalers to purchase hydrocodone products during the audit period. The compliance officers also observed that Bauder Pharmacy had ordered Hydrocodone APAP 7.5/500mg from 5 different suppliers in 1 day on 1 occasion; from 4 different suppliers in 1 day on 3 occasions; from 3 suppliers in 1 day on 18 occasions; and from 2 different suppliers in 1 day on 75 occasions. (Rhodes testimony; State Exhibit 7, pp. 49-50; Exhibit 16)

Compliance Officer Sue Mears contacted two of Bauder Pharmacy's wholesalers to determine if they had experienced shortages of hydrocodone products. Anda reported some shortages of 5/325 and 5/500 strengths of hydrocodone that past fall. A representative of Top RX did not report any shortages but told Mears that some manufacturers may be reducing production levels of products with 500mg of APAP because by 2014 the FDA will no longer allow these products on the market. The Top RX representative also told Mears that his company requires a pharmacy to submit a usage report for the prior 3 months when filling out an initial application. If the controlled substance dispensing exceeds 30% of prescription volume, Top RX will not sell any controlled drugs to the pharmacy. (State Exhibit 7, p. 50)

10. Pharmacies are required to maintain complete and accurate records of all purchases and all dispensing or disposal of controlled substances. The purchase records must show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The records of all controlled substances dispensed or otherwise disposed of must show the date of dispensing, the name and address of the person to whom or for whose use, and the kind and quantity of drugs dispensed.

Pharmacies are required to maintain all records of controlled substances for at least two years from the date of the transaction. Prescriptions for controlled substances are valid for six months following the date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following issue. Controlled substance prescriptions must be maintained for two years from the last date of refill.

Inventories and other records of Schedule III, IV, and V records shall be maintained either separately from all other records or in a form so that the required information is readily retrievable from the pharmacy's ordinary business records. (Rhodes testimony; See also Iowa Code sections 124.306, 155A.12(4); 657 IAC 10. 21, 10.34, 8.9)

Pharmacists Kim Robertson and Jay Wangerin and pharmacy technician Jennifer Higgins all confirmed that Bauder Pharmacy received invoices from wholesalers with the delivery of their prescription drug orders. Following delivery, the pharmacist is responsible for checking in the controlled substance order and for signing and dating the invoice to document the shipment that was received. Invoices must be maintained in the pharmacy's records for a minimum period of two years. Pharmacist Kim Robertson was responsible for checking in all Schedule II controlled substances at Bauder Pharmacy. Either Ms. Robertson or another pharmacist checked in all other controlled substances. Mr. Wangerin told Board investigators that if he checked in controlled substances he always initialed and dated the invoice. (Rhodes, Jessen, Higgins testimony; State Exhibits 29-32; 657 IAC 8.9(1))

At the time of the March 16, 2012 pharmacy inspection, Bauder Pharmacy had approximately twenty years of controlled substance records stored in boxes in an unsecured area of the basement. Jean Rhodes informed Mark Graziano that the Board required controlled substance records to be kept for two years although

insurance companies may require records for a longer period of time. Mr. Graziano asked Rhodes if he could shred records that were more than two years old if he was only keeping them for the Board, and she told him that he could. The March 22, 2012 Inspection Report authored by Jean Rhodes states, in part: *"The basement is also an area of storage for pharmacy records. Recommended to destroy some of the very old records as the Board of pharmacy typically needs records for two years and insurance companies possibly for 10 years. Some records may be close to twenty years old that are stored in the basement."* (Rhodes, Mears testimony; State Exhibit 11, p. 58)

At hearing, Mark Graziano testified that the West Des Moines Lions Club shredded some of his old records on April 27, 2012. Mr. Graziano provided a receipt from the Lions Club showing that he paid \$200 for the "shred-it" on April 27, 2012. Mr. Graziano also testified that Jean Rhodes and/or the Board shredded his documents. This was not true. (Graziano, Rhodes testimony; Respondent Exhibit H)

Service of the Board's Statements of Charges, Orders, and Administrative Search Warrant

11. On May 3, 2012, the Board signed and issued an Order of Immediate Suspension and Order to Show Cause that immediately suspended Bauder Pharmacy Inc.'s controlled substance registration (number 1100280). The Board also found probable cause to file a Statement of Charges against Bauder Pharmacy, Inc., which alleged nineteen violations of state statutes and the Board's rules. (State Exhibits 4, 6) Also on May 3, 2012, the Board issued an Emergency Order that immediately suspended the pharmacist license (number 16752) issued to Mark Graziano. The Board also issued a Statement of Charges against Mark Graziano, which alleged 20 violations of state statutes and the Board's rules. (State Exhibits 1, 2)

On May 10, 2012, Jean Rhodes personally served the immediate suspension orders and the statements of charges on Bauder Pharmacy, Inc. and Mark Graziano. An administrative search warrant was served at the same time. The Board's Executive Director, several of the Board's compliance officers, and Matthew Sauer of the Iowa Division of Criminal Investigation (DCI) Cyber Crime Unit accompanied Rhodes to Bauder Pharmacy on May 10, 2012. (Rhodes, Jessen testimony; State Exhibit 28)

Mr. Sauer made a forensic image of the pharmacy's computer. Board staff seized all of the pharmacy's controlled substance records from January 1, 2008 through May 10, 2012 and all controlled substance medications. Pharmacist Kim Robertson and pharmacy technician Jennifer Higgins assisted the Board's compliance officers in attempting to locate the controlled substance records and medications, which were located throughout the pharmacy and in the basement of the building. Jean Rhodes told the pharmacy's employees to contact the Board if they located any additional controlled substance records for the relevant time period. The seized records and medications have been stored by the Board in locked, secure storage since May 10, 2012. (Rhodes, Jessen testimony; State Exhibit 28, pp. 492-493)

On May 10, 2012, the Board's compliance officers interviewed all Bauder Pharmacy employees, except Mark Graziano. The employees provided signed and witnessed voluntary statements and their interviews were also video recorded. The only employees who reportedly handled controlled substances as part of their duties were full-time pharmacists Mark Graziano and Kim Robertson, part-time pharmacist Jay Wangerin, and pharmacy technician Jennifer Higgins.

The employees reported that either Mark Graziano or Kim Robertson ordered controlled substances from the wholesalers. Kim Robertson checked in all Schedule II controlled substances. When asked how many wholesalers were used by the pharmacy to order controlled drugs, pharmacist Jay Wangerin identified 4 wholesalers and pharmacist Kim Robertson identified 3 wholesalers. (Rhodes testimony; State Exhibits 28, pp. 492-493; Exhibits 29-34)

Kirby Small Interviews and Testimony at Hearing

12. On May 11, 2012, Kirby Small called the Board office and identified himself as the person who had previously made the anonymous telephone complaint against Bauder Pharmacy. Jean Rhodes and Sue Mears interviewed Kirby Small that day, and he told them that he would be willing to testify. Ms. Rhodes took notes during this first interview. (State Exhibit 35) On May 15, 2012, Rhodes and Mears conducted a second interview of Kirby Small, which was video recorded. (State Exhibit 36)

During his two interviews, Kirby Small told the compliance officers that he was present many times when Mark Graziano would pass a box containing bottles of

hydrocodone APAP 7.5/500mg out the pharmacy's back door to a person that Small initially identified only as the "General." [Later in his interview, Kirby Small confirmed the identity of the General as well as two other persons he claimed were involved in the distribution of the hydrocodone] Mr. Small told Rhodes and Mears that he believed Mark Graziano had been illegally distributing hydrocodone since at least since 2005. Small believed that Mark Graziano used the money to cover his gambling losses and to pay for expensive cars. (Rhodes, Small testimony; State Exhibits 35, 36)

Kirby Small told Rhodes and Mears that he had been using 15-20 hydrocodone tablets a day for years and would receive 100 hydrocodone tablets from the General every week. Small told them that prior to making his anonymous report, the General and Mark Graziano refused to give him any more hydrocodone because he was unable to pay them. Mr. Small reports that after the General cut him off, he confronted Mark Graziano in the Bauder Pharmacy parking lot and told Graziano that he "knew everything." When Mark Graziano responded by telling Small that he did not know what he was talking about, Small admits he "went crazy" and told Graziano that he would not be able to "keep doing this."

According to Mr. Small, Pharmacist Kim Robertson came out to the parking lot and told Mark he had a telephone call. After Mark went back inside the pharmacy, Small told Kim that Mark was selling hydrocodone out the back door of the pharmacy and would "ruin you." Kim reportedly told Small "you need help." According to Mr. Small, Mark Graziano later called and threatened him with sending some "guys" over to his house. Mr. Small did not believe this threat, and no one ever came to his house. (Rhodes, Small testimony; State Exhibits 35, 36)

Kirby Small reported that he was forced to go "cold turkey" and stop taking hydrocodone after the General and Mark Graziano cut off his supply. He reports that he spent three days on the couch, "jonesing" and was unable to eat. After he was finally free of the drugs and felt better, Mr. Small realized how much the hydrocodone had damaged his life and how much it was hurting others. This motivated him to come forward and testify. (State Exhibits 35, 36; Small testimony)

During his interview, Kirby Small admitted that he was on criminal probation for a "Department of Human Services thing" at the time he confronted Mark

Graziano. On cross-examination at hearing, Kirby Small admitted that he had been convicted of elderly abuse for misusing his father's money. Mr. Small believes that Mark Graziano or the General called his probation officer to report that he had been smoking marijuana. Mr. Small was arrested for a probation violation and sent to jail for 15 days. If his probation had been revoked, Mr. Small would have been required to serve a five year prison sentence. Mr. Small admits this is what prompted him to make the initial anonymous telephone call to the Board in late September, 2011. Kirby Small later identified himself as the anonymous complainant after seeing the news report on the Board's visit to the pharmacy and filing of charges. (Small testimony; State Exhibit 28, p. 494; Exhibits 35, 36)

At hearing, Kirby Small described what happened the times that he went with "the General" to Bauder Pharmacy to pick up the hydrocodone. Mr. Small testified that he and the General would be out for coffee on a Saturday morning, and the General would call Mark Graziano to arrange the pick-up. Mr. Small testified that the hydrocodone pick-up usually occurred after 9:00 a.m. because the UPS truck delivered the hydrocodone to the pharmacy at around 9:00 a.m. (Small testimony; State Exhibits 35, 36)

Kirby Small testified that on some occasions he drove around to the back of the pharmacy and waited outside while the General went in the back door of the pharmacy to get the hydrocodone. Other times, he would drop the General off at the front of the pharmacy and then drive around to the back of the pharmacy to wait for him. The General would come out the pharmacy's back door with a box containing 2-3 white stock bottles of 7.5mg hydrocodone. The "General" removed the labels from the bottles and got rid of them. Small testified that after the pick-up, he sometimes helped the General count the pills. After one of the pill counting sessions, Mr. Small kept one of the pharmacy stock bottles as a "souvenir." He brought the stock bottle, which did not have any label on it, to his interview at the Board office and to the hearing.⁴ (Small testimony; State Exhibit 79)

⁴ In his statements and in testimony at hearing, Mr. Small sometimes described the 7.5mg hydrocodone stock bottles as containing 5000 tablets and sometimes described them as containing 500 tablets. The hearing record does not contain any documentation that Bauder Pharmacy ever received stock bottles containing 5000 tablets, but there are many records for stock bottles containing 500 tablets. The stock bottle provided by Mr. Small (State Exhibit 79) appeared consistent in size with a 500 tablet stock bottle.

Kirby Small was unclear on how many times he went with the General to Bauder Pharmacy for the hydrocodone pick up. Initially, he testified that he went with the General probably no more than 10 times but later clarified that he meant "at least" 10 times. Mr. Small testified that the General also picked up hydrocodone from Bauder Pharmacy on many other occasions without him. (Small testimony)

At hearing, Mark Graziano denied ever having anything to do with Kirby Small other than filling his prescriptions and allowing Small to do some painting at his home when Small was unable to pay his bill at the pharmacy. Mr. Graziano admitted that he and Kirby Small know some people in common, but denied illegally distributing hydrocodone and denied that he ever threatened Kirby Small. (Small, Graziano testimony)

***Bauder Pharmacy Audit Using Wholesaler Records and Computer Records
from 1/1/08-3/21/12 [Second Audit]***

13. After the administrative search warrant was executed, Jean Rhodes and Sue Mears conducted a second audit using the invoices subpoenaed from Bauder Pharmacy's wholesalers, the invoices seized from Bauder Pharmacy, and the actual controlled substance dispensing records from the pharmacy's computer. The results of the second audit are summarized in State Exhibit 28. The second audit revealed that for the period from January 1, 2008 to March 12, 2012:

- The wholesaler verified invoices show that Bauder Pharmacy ordered and received a total of 1,049,300 hydrocodone APAP tablets (all brands, all strengths). Of these, 495,311 tablets were hydrocodone APAP 7.5/500;
- PMP records indicate that Bauder Pharmacy dispensed 359,313 hydrocodone APAP tablets (all brands, all strengths) to customers;
- There were 689,987 hydrocodone APAP tablets that were ordered and shipped to Bauder Pharmacy by wholesalers that could not be accounted for through the pharmacy's computerized dispensing records.

(Rhodes testimony; State Exhibit 28, pp. 495-496)

14. Rhodes and Mears created detailed spreadsheets comparing and analyzing the information obtained in the two audits. State Exhibits 37-44 are spreadsheets that list every wholesaler invoice and indicate whether the invoice was reported to ARCOS, whether it was provided by the wholesaler in response

to the Board subpoena, and whether the same invoice was found in the records maintained by Bauder Pharmacy. (Rhodes testimony; State Exhibits 37-55)

a) Auburn was the only wholesaler that was unable to provide invoices for the entire audit period because it only had invoices going back as far as November 4, 2009. Because of this, the second audit was unable to verify 33,500 hydrocodone tablets that Auburn reported to ARCOS as having been ordered by Bauder Pharmacy in 2008 and was unable to verify 33,000 hydrocodone tablets from 2009. These unverified tablets were not included in the second audit and resulted in a lower number of purchases than those that had been reported in ARCOS. (State Exhibit 28, p. 495; Rhodes testimony)

b) For calendar year 2008, wholesaler Masters Pharmaceutical provided five invoices in response to the Board's subpoena that it had not been previously reported to ARCOS. These invoices were for an additional 2000 tablets of hydrocodone APAP 5/500mg and 2000 tablets of 7.5/500mg. (State Exhibit 28, p. 495; State Exhibit 37, p. 519-520, 527-528).

c) For calendar year 2009, all of the wholesaler's invoices matched the orders reported to ARCOS with the exception of the invoices that Auburn had not retained. (State Exhibit 28, p. 495; Exhibit 38)

d) For calendar year 2010, wholesaler Dakota Drug provided an invoice for 1000 tablets of hydrocodone APAP 7.5/500mg that had not been reported to ARCOS. (State Exhibit 28, p. 495; Exhibit 39, pp. 585-586).

e) For calendar year 2011, the following drugs were reported to ARCOS but were later returned to the wholesalers by Bauder Pharmacy: 100 tablets hydrocodone APAP 10/325mg returned to Cardinal; 1000 tablets hydrocodone APAP 10/325mg returned to Top RX; and 1000 tablets hydrocodone APAP 7.5/500mg returned to Top RX. (State Exhibit 28, p. 495, Exhibit 40, pp. 597-598, 602).

f) For calendar year 2012, wholesaler Auburn provided two invoices in response to the Board's subpoena that had not been reported to ARCOS. These included an invoice for 2000 tablets of hydrocodone APAP 7.5/500mg and an invoice for 1000 tablets hydrocodone APAP 10/325mg. (State Exhibit 28, p. 496; Exhibit 41).

g) Bauder Pharmacy was missing 137 invoices for its purchases of 144,000 tablets of hydrocodone APAP 7.5/500mg product during calendar years 2010, 2011, and 2012. Bauder Pharmacy should have been able to provide these invoices because they fell within the two year period for retention of controlled substances records. (State Exhibit 28, p. 497).

h) Bauder Pharmacy was also missing its annual inventories of hydrocodone products. (State Exhibit 28, p. 496).

i) A total of 907 hydrocodone tablets that were documented as having been dispensed per Bauder Pharmacy's computer dispensing records had not been reported by Bauder Pharmacy to the PMP. (State Exhibit 28, p. 496)

(Rhodes testimony)

15. On June 20, 2012, Jean Rhodes and Sue Mears met with pharmacist Kim Robertson at Bauder Pharmacy. At this visit, Jean Rhodes reminded Ms. Robertson that the pharmacy still needed to identify a new pharmacist in charge. Rhodes and Mears showed Ms. Robertson the 2010 and 2011 invoices that she had signed and asked her if she could explain the large discrepancy between the amount of hydrocodone APAP 7.5/500mg that she was signing for each month and the small amount that the pharmacy was dispensing.

- In 2010, Kim Robertson signed invoices for receipt of a total of 62,500 tablets of hydrocodone APAP 7.5/500mg, but the pharmacy's records showed that only 14,949 tablets had been dispensed. This meant that 47,551 tablets were not accounted for;
- From January to September of 2011, Kim Robertson signed invoices for a total of 58,500 tablets of hydrocodone APAP 7.5/500mg, but the pharmacy's records showed that 7,532 tablets were dispensed. This meant that 50,968 tablets were not accounted for.

Kim Robertson denied that any drug diversion was going on at the pharmacy and told Rhodes that she would only order the hydrocodone if there were prescriptions for it. Ms. Robertson also questioned whether the computer records could be wrong and asked to see the invoices. (Rhodes testimony; Exhibit 28, p. 496-497; Exhibits 43-44)

Jean Rhodes also informed Kim Robertson that the pharmacy had a large number of missing invoices and that the annual inventories of hydrocodone products were also missing. Ms. Robertson replied that she was sure the inventories were in the yellow notebook or in the front of the perpetual CII log. Rhodes and Mears returned to the secure storage area where the Bauder Pharmacy records were being kept and reviewed the CII perpetual log and the yellow notebook. The hydrocodone inventories were not there. (Rhodes testimony; Exhibit 28, p. 496)

16. On July 23, 2012, Bauder Pharmacy submitted a pharmacist in charge (PIC) change naming Kim Robertson as the new PIC. (Rhodes testimony; State Exhibit 56, p. 753-754)

Review of Randomly Selected Prescriptions Filled by Bauder Pharmacy 2008-2012

17. Jean Rhodes and Sue Mears reviewed 614 randomly selected prescriptions that had been filled by Bauder Pharmacy between 2008 and 2012. Only 166 of the 614 prescriptions met all of the legal requirements for prescriptions. The various deficiencies on these prescriptions included:

- Sender's information cut off from fax;
- Wrong patient;
- Wrong prescriber;
- Wrong medication;
- No prescriber signature or verification;
- Wrong number of refills;
- Wrong directions;
- No prescriber DEA number for controlled substances;
- Faxed prescription not signed by prescriber;
- Wrong dispensed quantity;
- Filled beyond authorized time period;
- Filled prior to authorization;
- RX denied by prescriber but filled by pharmacy;
- No prescribed quantity;
- RX number not recorded on prescription;
- Dispensed generic when prescription indicated "Do not substitute."

(Rhodes testimony; State Exhibit 56, pp. 753-755; Exhibits 57-61)

18. Jean Rhodes and Sue Mears conducted a separate review of the Androgel prescriptions filled by Bauder Pharmacy after their invoice review revealed frequent purchases of Androgel by the pharmacy. Androgel (testosterone) is a Schedule III controlled substance. Rhodes and Mears reviewed a total of 95 Androgel prescriptions filled by Bauder Pharmacy between 2010 and 2012. Only 3 of the 95 prescriptions were found to be legally correct. The deficiencies on the Androgel prescriptions included:

- No Dr. DEA number;
- No hardcopy in file;
- No prescriber signature;
- Stamped prescriber signature;
- Unauthorized refills dispensed;
- Refilled beyond 6 months;
- Initial fill after the prescription had expired (6 months);
- No patient name on hard copy prescription;
- No notation of verbal authorization;
- No RX number on prescription;
- Sender information cut off from fax;
- Wrong dosage form of medication;
- Filled prior to receipt of fax authorization.

(Rhodes testimony; State Exhibit 56, pp. 755-756; State Exhibits 62-64)

19. Jean Rhodes and Sue Mears visited the physician offices for three patients who had Androgel prescriptions filled by Bauder Pharmacy between August 2009 and April 2012. The purpose of these visits was to verify the validity of the prescriptions.

a) Bauder Pharmacy filled 9 prescriptions for Androgel in the name of Patient #1 between January 25, 2010 and April 21, 2012. Patient #1's physician's office could only verify 4 of the prescriptions. Bauder Pharmacy had dispensed a total of 420 unauthorized 1% 5gm gel packets in the name of this patient.

b) Bauder Pharmacy filled 6 prescriptions for Androgel in the name of Patient #2 between January 20, 2010 and April 30, 2012. Patient #2's physician's office could only verify 3 of the prescriptions. Bauder Pharmacy had dispensed a total of 600 unauthorized 1% 5gm gel packets in the name of this patient.

c) Bauder Pharmacy filled 8 prescriptions for Androgel in the name of Patient #3 between August 15, 2009 and April 30, 2012. Patient #3's physician's office could only verify 5 of the prescriptions. Bauder Pharmacy had dispensed a total of 450 unauthorized 1% 5gm gel packets in the name of this patient.

(Rhodes testimony; State Exhibit 56, p. 756; State Exhibit 65)

Review of Prescriptions for CG

20. During the initial audit, Jean Rhodes noted that CG was the only patient receiving brand name Lortab (Hydrocodone and Acetaminophen 7.5/500mg) from Bauder Pharmacy, and there were several early refills. CG is a family member of Mark Graziano. Jean Rhodes contacted CG's physician's office in an attempt to verify if he had authorized the patient's Lortab prescriptions. She obtained statements from the physician's staff members but it is unclear if she ever spoke to CG's physician. Ms. Rhodes determined that since July 18, 2011, Bauder Pharmacy had filled 5 unauthorized prescriptions for CG and had provided an additional 8 unauthorized refills. (Rhodes testimony; State Exhibit 56, pp. 756-757; Exhibit 66-69)

At hearing, Respondents submitted a February 25, 2013 letter from CG's physician, in which he states that he first met CG in January 2009. According to the letter, CG was on Alprazolam and hydrocodone when the physician first met her, still is, and has been as long as he has known her. (Respondent Exhibit L) Respondents also submitted a March 6, 2012 prescription written by the physician for CG for hydrocodone/acetaminophen 7.5/500. (Respondent Exhibit M)

At hearing, Mark Graziano testified that CG is usually accompanied to her doctor appointments by one of her four family members who are licensed pharmacists. Mr. Graziano further testified that it is not unusual for the physician to give direct verbal authorization for CG's prescriptions to one of the pharmacists in CG's family. (Graziano testimony)

Rhodes' Return to Bauder Pharmacy on October 11, 2012

21. On October 11, 2012, Jean Rhodes revisited Bauder Pharmacy and met with pharmacist in charge Kim Robertson to review the deficiency corrections

from the March 22, 2012 Inspection Report. Mark Graziano was behind the pharmacy counter when Ms. Rhodes entered the store. Ms. Robertson denied that Mr. Graziano was performing any pharmacist duties and told Rhodes that he was helping with the billing.

Ms. Rhodes asked to see the pharmacy's policies and procedures manual. Ms. Robertson checked with Mr. Graziano and they both claimed that the Board had taken the policies and procedures with all of the other records. Mr. Graziano stated that the policies and procedures were in the back of a black book. Following the visit, Ms. Rhodes reviewed the records in the Board's possession. The only black book was the daily controlled substance refill log. She then notified Ms. Robertson that the Board does not have possession of the pharmacy's policies and procedure manual. (Rhodes testimony; State Exhibit 70, pp. 815-816)

The pharmacy still did not have a Continuous Quality Improvement (CQI) program at the time of Rhodes' revisit, nor did it have a documented technician training policy. Ms. Rhodes also needed to verify that no legend medications or pharmacy records were being stored in the unsecured basement. Mr. Graziano had previously reported that medications had been sent to a reverse distributor and that someone was coming to destroy records. Upon checking the basement, Ms. Rhodes found hardcopy prescriptions from 2007 and also found shelves of older medications. (Rhodes testimony; State Exhibit 70, pp. 815-816; Exhibits 71A, 72, 73)

Respondents' Evidence at Hearing

22. Pharmacy technician Jennifer Higgins has been employed by Bauder Pharmacy for eight years. Ms. Higgins testified that Kim Robertson was primarily responsible for checking in the shipments of controlled substances to the pharmacy. If Ms. Higgins opened a tote from a wholesaler and saw controlled substances in it, she would give the shipment to Ms. Robertson. Ms. Higgins was working at Bauder Pharmacy when Jean Rhodes conducted the March 16, 2012 inspection. Ms. Higgins testified that she was present when Ms. Rhodes presented Kim Robertson with a "stack" of unsigned invoices that had been collected and told her to sign them. Ms. Higgins did not actually observe Ms. Robertson sign these invoices. (Higgins testimony)

Only a pharmacist could place an order for a controlled drug at Bauder Pharmacy. After the controlled substances were checked in, Ms. Higgins might help put Schedule III-V controlled substances on the shelf. She estimated that they usually had about 2-3 bottles of 7.5/500 mg hydrocodone on the shelf at one time. Ms. Higgins never observed anyone take a stock bottle of hydrocodone out the back door of the pharmacy. (Higgins testimony)

23. In his testimony at hearing, Mark Graziano admitted that at the time of the March 16, 2012 pharmacy inspection:

- Jennifer Higgins' pharmacy technician registration had been expired since September 30, 2010. Mr. Graziano testified that he did not realize it had expired but admitted that as the PIC he was responsible for Ms. Higgins;
- Bauder Pharmacy did not have written policies and procedures, which are the responsibility of the PIC;
- There were outdated medications that were in an unsecured location in the basement;
- He was not wearing his identification badge. Mr. Graziano testified that he did not think the ID badge was necessary because all of his customers know him;
- All of the pharmacy's invoices were not signed;
- The only documentation of pharmacy technician training was on a notecard;
- The pharmacy did not have a written Continuous Quality Improvement (CQI) program. Mr. Graziano further admitted that he did not even know that a CQI program was required;
- There were a number of deficiencies involving the pharmacy's sterile compounding, including violations of the rules requiring: policies and procedures, a quality assurance program, documentation of training, and environmental testing. Mr. Graziano testified that he had been doing sterile compounding for four years but was not familiar with the federal rules for sterile compounding (USP 797) and had little knowledge of the Board's rules on sterile compounding.

(Graziano testimony)

24. Mark Graziano admits that as PIC, he was responsible for the security of the pharmacy and for establishing policies and taking steps to prevent illegal

diversion of drugs. Mr. Graziano provided the following testimony concerning the pharmacy's process for ordering and receiving controlled drugs:

- Mr. Graziano ordered controlled substances for the pharmacy, although the other two pharmacists could also place orders. He placed orders in one of three ways: in response to a telephone solicitation by a wholesaler's sales representative, on-line through the wholesaler's website, and by telephone. The majority of orders were placed by phone;
- When orders were placed on-line through a website, the person placing the order had to enter a User ID and a password. Mr. Graziano had trouble remembering his User ID and passwords and kept them on a "cheat" sheet underneath his computer;
- The majority of the pharmacy's controlled substance purchases were linked to the VISA credit card issued in the name of Mark Graziano/Bauder Pharmacy. The credit card had a \$50,000 limit, but the monthly charges on it were sometimes as high as \$75,000; and
- The controlled substance orders were delivered by various carriers and would arrive in either a tote or a box with the invoice. Kim Robertson was primarily responsible for checking in the controlled substance orders and signing off on the invoice, although any pharmacist could check them in. The invoices were filed in the basement.

Mark Graziano denies ever illegally dispensing hydrocodone from Bauder Pharmacy without a prescription and denies all of the claims of illegal distribution of hydrocodone made by Kirby Small. Mr. Graziano testified that he did not know that any drugs were missing from the pharmacy prior to May 2012 and if he had known, he would have notified the Board and the DEA. (Graziano testimony)

When asked how he explained the hydrocodone that could not be accounted for through the pharmacy's records, Mr. Graziano testified that the Board "made him" shred his older records. Mr. Graziano testified that the missing invoices were probably in the wrong box and likely were shredded in late April 2012. He suggests that the missing invoices would help exonerate him of the charges of illegally dispensing hydrocodone. (Graziano testimony)

Mark Graziano testified that there were occasions when it appeared to him that someone had tampered with the security tape on boxes delivered to the pharmacy. Mr. Graziano estimated that Bauder Pharmacy received boxes from

wholesalers that appeared to have been tampered with on 10-20 occasions. Mr. Graziano further testified that when this happened he refused to accept the shipment and notified the manufacturer. Mr. Graziano never reported any tampering or missing drugs to the police or to the Board. (Graziano testimony)

Mark Graziano also testified that drug orders were sometimes shipped to Bauder Pharmacy in error. He submitted documentation of one incident that occurred in January 2013. Dakota Drug mistakenly sent a shipment of hydrocodone APAP TB 10/235 to Bauder Pharmacy, when the shipment was intended for a pharmacy in Mason City. Bauder Pharmacy immediately notified the Board and Dakota Drug of the error, and the shipment was returned. Mr. Graziano questioned how Dakota Drug would have reported the order to ARCOS if Bauder Pharmacy had not alerted the Board. (Respondent Exhibit F; Graziano testimony)

After this mistake was reported, Jean Rhodes contacted Dakota Drug to inquire if these types of errors were very common. The shipping supervisor advised Rhodes that packages must go through at least three people prior to shipment, but that there is always the possibility of human error. He was not aware of any statistics that the company kept on errors. (State Exhibit 75)

Mark Graziano further testified that someone has had unauthorized access to his VISA credit cards, and he believes that his credit cards may have been used by someone else to order hydrocodone from his wholesalers. Mr. Graziano provided three partial VISA credit card statements (May 2010, April 2011, and May 2012) issued in the name of Mark E. Graziano/Bauder Pharmacy. The three credit card statements all had different account numbers. Mr. Graziano testified that he had to open the new accounts because the old accounts had been "tampered with." (Graziano testimony)

Mark Graziano did not explain what caused him to believe that the credit card accounts had been tampered with, and he did not provide any other information concerning these accounts. Mr. Graziano admits that even after he believed that his credit card accounts had been compromised, he never compared his billing statements to his invoices to check for improper charges. He testified that he just assumed that any charges on his credit cards from his drug wholesalers were legitimate. Mr. Graziano testified that he did not connect the compromise of his credit cards to the hydrocodone shortages until just a few days prior to hearing. At hearing, Mr. Graziano suggested that someone who worked at the pharmacy

may have used his credit card to purchase controlled substances. (Graziano testimony)

CONCLUSIONS OF LAW

Board's Authority to Discipline Licensees and Registrants

The Board is authorized to discipline pharmacists and pharmacies for any violation of Iowa Code chapters 155A, 124 or any rule of the Board. Specifically, Iowa Code section 155A.15(2)(c) and (h) authorize the Board to impose discipline, including but not limited to revocation, if it finds that a *licensed pharmacy* has:

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

...

h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

Iowa Code section 124.304(1)(d) also authorizes the Board to suspend, revoke, or restrict a controlled substances registration, issued under section 124.303 to manufacture, distribute, or dispense a controlled substance, upon a finding that the registrant committed such acts as would render the registrant's registration under section 124.303 inconsistent with the public interest, as determined under that section. The Board may suspend any registration simultaneously with the institution of disciplinary proceedings under section 124.304 if it finds that there is an imminent danger to the public health and safety which warrants this action.⁵

Iowa Code section 124.303(1) sets out the factors that the Board may consider in determining whether issuance of a controlled substance registration would be inconsistent with the public interest. The factors include, in relevant part: the registrant's maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels and the registrant's compliance with applicable state and local law.

⁵ Iowa Code section 123.305(2).

Iowa Code section 155A.12(1), (4), and (5) authorize the Board to impose discipline, including revocation, on any *licensed pharmacist* who:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.
- ...
4. Failed to keep and maintain complete and accurate records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.
5. Violated any provision of the controlled substances Act or rules relating to that Act.

Iowa Code section 17A.18 and 657 IAC 35.30 authorize the Board to issue an Emergency Adjudicative Order taking immediate action to suspend a license or registration when necessary to prevent or avoid immediate danger to the public health, safety or welfare.

***Count I : Bauder Pharmacy and Mark Graziano
Failing To Maintain Effective Controls and Accountability Over Controlled
Substances***

Iowa Code section 124.402(1) (a) provides that it is unlawful for any person, subject to Division III (Regulation of the Manufacture, Distribution, and Dispensing of Controlled Substances), to distribute or dispense a controlled substance in violation of section 124.308. Iowa Code section 124.308(4) prohibits pharmacies from dispensing a controlled substance included in Schedule III or IV without a written or oral prescription of a practitioner or without an electronic or facsimile prescription in accordance with subsection 5. The prescription for a Schedule III Controlled Substance may not be filled or refilled more than six months after its issue date and may not be refilled more than five times, unless renewed by the practitioner.

A substance is placed in Schedule III if it has a potential for abuse that is less than that of substances in Schedules I and II, if the substance has a currently accepted medical use in treatment, and if abuse of the substance may lead to

moderate or low physical dependence or to high psychological dependence.⁶ Hydrocodone is a narcotic drug that has been placed in Schedule III.⁷

657 IAC 36.1(ac) authorizes the Board to discipline any licensee, registrant, or permittee who fails to create and maintain complete and accurate records as required by state or federal law, regulation or rule of the Board.

The preponderance of the evidence established that Respondent Bauder Pharmacy violated Iowa Code sections 155A.15(2)(c) and (h), 124.402(1), 124.308 and 657 IAC 36.1(4)(ac) when it failed to maintain adequate control over and accountability for controlled substances by failing to keep and maintain all required records of controlled substances and by failing to prevent loss or diversion of controlled substances from the pharmacy.

The preponderance of the evidence established that Respondent Mark Graziano violated Iowa Code sections 155A.12(1),(4), and (5), 124.402(1), 124.308 and 657 IAC 36.1(4)(ac) when he failed to maintain adequate control over and accountability for controlled substances by failing to keep and maintain all required records and by failing to prevent loss or diversion of controlled substances from the pharmacy. As the pharmacist in charge (PIC), Mark Graziano was responsible for maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs.⁸ He was also responsible for establishing and maintaining effective controls against the theft or diversion of prescription drugs and for maintaining records for such drugs.⁹

The preponderance of credible evidence in the record established that Bauder Pharmacy is unable to account for over 650,000 tablets of hydrocodone it received during the period of time covered by the Board's two audits. Board staff conducted painstaking and detailed audits to identify this large number of unaccounted for hydrocodone tablets. The two audits yielded very similar results when the missing invoices from wholesaler Auburn (those before November 4, 2009) are taken into account. The first audit indicated that Bauder Pharmacy could not account for 740,888 hydrocodone tablets, while the second audit indicated that Bauder Pharmacy could not account for 689,987

⁶ Iowa Code section 124.207.

⁷ Iowa Code section 124.208(5).

⁸ 657 IAC 6.2(12).

⁹ 657 IAC 6.2(13).

hydrocodone tablets. It is impossible to calculate a precise count of the missing hydrocodone, due in large part to Respondents' repeated failures to properly create and maintain accurate records for controlled substances. Nevertheless, overwhelming evidence established that a gross quantity of hydrocodone tablets have been illegally diverted from Bauder Pharmacy and/or were dispensed from the pharmacy in violation of Iowa Code chapters 124, 155A, and the Board's rules. The preponderance of the credible evidence in the record further established that pharmacist in charge Mark Graziano was involved in the illegal diversion of large quantities of hydrocodone from Bauder Pharmacy.

Mark Graziano testified that he "stands by" the accuracy of the controlled substance dispensing reports that he made to the PMP. In fact, the number of hydrocodone prescriptions recorded on Bauder Pharmacy's computer system for the period of the audit was quite close to the number of hydrocodone prescriptions reported by Bauder Pharmacy to the PMP. (358,012 v. 359,313 tablets dispensed).

The number of hydrocodone tablets that Bauder Pharmacy dispensed by prescription stands in stark contrast to the far larger numbers of hydrocodone that Bauder Pharmacy ordered from wholesalers over the same period (per ARCOS records-1,098,900 hydrocodone tablets; per wholesaler verified invoices-1,049,300 tablets). Mark Graziano does dispute the accuracy of the ARCOS records, however. Through the second audit examining the actual invoices, the Board's compliance officers did identify a few errors in the ARCOS reports (although the errors were reporting omissions.) Nevertheless, it is also clear that the number of reporting errors is likely very small in comparison to the number of transactions that wholesalers reported. Errors in the ARCOS reports cannot possibly account for the huge discrepancies between Bauder Pharmacy's hydrocodone orders and its dispensing records.

As the pharmacist in charge, Mark Graziano was responsible for ensuring that Bauder Pharmacy created and maintained all required controlled substance records. State statutes and Board rules require most of these records, including invoices, to be kept for a minimum period of two years. The records are required to be organized and readily retrievable by an agent of the Board.

Mark Graziano made repeated claims throughout his testimony suggesting that either Jean Rhodes or the Board shredded his records, thereby undermining his ability to defend himself against these charges. This is completely untrue and

unsupported by the record. When Jean Rhodes arrived at Bauder Pharmacy to conduct the inspection on March 16, 2012, the pharmacy's controlled substance records were neither organized nor readily retrievable. A large number of records, including confidential patient records and other records close to 20 years old, were improperly stored in an unsecured area of the pharmacy's basement. Ms. Rhodes reasonably advised Mr. Graziano that he should get rid of some of the older records, and her inspection report clearly states, in bold print, that insurance companies may require records for up to 10 years. There is no evidence that Ms. Rhodes or the Board destroyed any records or directed Mr. Graziano which records he should destroy. Mr. Graziano submitted his \$200 receipt from the West Des Moines Lion Clubs for shredding some of the records. Mr. Graziano is the person responsible if records were misfiled and destroyed because he failed to verify the contents of boxes that he gave to the shredder.

As the pharmacist in charge and the person primarily responsible for ordering the hydrocodone, Mark Graziano must have been known the enormous numbers of hydrocodone tablets that Bauder Pharmacy was ordering from wholesalers. Over the period of the audit, Mr. Graziano ordered hydrocodone from 14 different wholesalers and frequently ordered hydrocodone from multiple different wholesalers in a single day. It is obvious to the Board that this was a strategy employed by Mark Graziano to try to conceal the large numbers of hydrocodone that he was ordering. It is significant that when Jean Rhodes asked Mark Graziano how many wholesalers he used to order controlled substances, he reported using only 4 wholesalers. Bauder's two other pharmacists reported that the pharmacy used 3 or 4 wholesalers. The wholesaler records show, however, that Bauder Pharmacy had in fact ordered hydrocodone from 7 different wholesalers in the first three months of 2012. (State Exhibit 41) In 2011, Bauder Pharmacy ordered hydrocodone from 11 different wholesalers. (State Exhibit 40) In 2010, Bauder Pharmacy ordered hydrocodone from 8 different wholesalers. (State Exhibit 41)

Some hydrocodone shipments may have arrived at Bauder Pharmacy in boxes that were damaged or appeared to have been tampered with. Some controlled substances may have been shipped to Bauder Pharmacy in error. The Board is convinced, however, that this would have constituted a very small percentage of the overall number of hydrocodone shipments to Bauder Pharmacy. Moreover, Mark Graziano and Bauder Pharmacy were responsible for ensuring that all controlled substance shipments received at the pharmacy were checked against invoices for accuracy before the invoices were signed and dated. This is an

essential step in maintaining accurate records. Mark Graziano and Bauder Pharmacy were required to properly report and document any missing drugs or any return of drugs received in error.

In his testimony, Mark Graziano suggested that an unnamed employee could have had access to his user name and password and could have ordered hydrocodone from wholesalers using his credit card, which he reports was compromised three years in a row. This testimony was neither credible nor plausible. Mr. Graziano provided no evidence to show that his credit card had ever been used to make hydrocodone purchases that he did not authorize. If the Bauder Pharmacy credit card had been compromised as Mark Graziano claims, it is completely implausible that he, as a small business owner, would continue to pay credit card balances in the range of \$50,000 every month without ever checking his statements for errors or unauthorized charges. Finally, as the pharmacist in charge Mr. Graziano was responsible for ensuring that proper security controls were in place for the pharmacy. This includes taking reasonable steps to protect his user name, password, and the credit card he had authorized to be charged for hydrocodone purchases.

Although there were some inconsistencies in Kirby Small's statements and testimony, the Board ultimately determined that Mr. Small's statements and testimony about the illegal distribution of hydrocodone from Bauder Pharmacy were more reliable and more plausible than Mark Graziano's denials. Mr. Small initially reported Mark Graziano's illegal distribution of hydrocodone in an anonymous telephone call to the Board nearly six months before the Board's first audit that revealed the large numbers of missing hydrocodone tablets.

From his first contact with Board staff, Mr. Small readily admitted that he was a drug user who was addicted to hydrocodone. After the Board's charges were made public, Mr. Small came forward to the Board and identified himself and also named others allegedly involved in the illegal distribution. He admitted that he had a criminal record. Mr. Small had nothing to gain from going public with his report, and he risked possible retribution and prosecution. Mr. Small has provided the only plausible explanation for what happened to the hundreds of thousands of hydrocodone tablets that Mark Graziano and Bauder Pharmacy cannot account for.

***Count II: Bauder Pharmacy and Mark Graziano
Inadequate Security and Failure to Establish Effective Controls Against
Diversion***

657 IAC 10.15 requires all registrants to provide effective controls and procedures to guard against theft and diversion of controlled substances. The rule sets forth a number of factors for the Board to consider when evaluating a registrant's security system. The factors with particular relevance to this case include: the adequacy of supervision over employees having access to controlled substances and storage areas, the extent of unsupervised public access to the facility, and the adequacy of the registrant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances. 657 IAC 10.15(2)"i,""j," and "m."

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.15 by failing to provide effective controls and procedures to guard against the theft and diversion of controlled substances. All of the reasons cited in connection with Count I also support a finding of violation under this count. Bauder Pharmacy's system for monitoring the receipt, distribution, and disposition of controlled substances was wholly inadequate. In addition, Respondents stored expired controlled drugs in an unlocked and unsecured area of the basement, which could potentially be accessed by unlicensed employees and the public.

***Count III: Bauder Pharmacy and Mark Graziano
Failure to Keep and Maintain Records Required by the Controlled Substances
Act***

Iowa Code section 124.306 provides that persons registered to manufacture, distribute, dispense or administer controlled substances under Iowa Code chapter 124 shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and such additional rules as may be issued by the Board. A practitioner who engages in dispensing any controlled substances to the practitioner's patients shall keep records of receipt and disbursements of such drugs, including dispensing or other disposition, and information as to controlled substances stolen, lost, and destroyed. In every such case the records of controlled substance received shall show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all

controlled substances dispensed or otherwise disposed of, shall show the date of dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were dispensed and the kind and quantity of drugs dispensed.

“Practitioner” is statutorily defined to include a pharmacy. Iowa Code section 124.101(26)(b).

Iowa Code section 124.306 further provides that every such record shall be kept for a period of two years from the date of the transaction recorded. Records of controlled substances lost, destroyed or stolen, shall contain a detailed list of the kind and quantity of such drugs and the date of discovery of such loss, destruction or theft. Iowa Code section 124.306.

The Board’s rules governing controlled substance record keeping are found at 657 IAC 10.34. The rules are consistent with Iowa Code section 124.306 but further provide that records must be kept by the registrant and available for inspection or copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in these rules.¹⁰ Controlled substance records shall be maintained in *readily retrievable manner* that establish the receipt and distribution of controlled substances. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a *secure storage area* outside the licensed pharmacy department, but the remote storage area shall be located within the same physical structure containing the licensed pharmacy department. 657 IAC 10.34 (emphasis added). 657 IAC 8.9 includes these same requirements.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated Iowa Code section 124.306 and 657 IAC 10.34 by failing to create and maintain required documentation of the pharmacy’s invoices for the purchase of hydrocodone and for failure to maintain annual inventories of its hydrocodone products. Respondents failed to ensure that invoices were properly signed and dated and failed to maintain controlled substances invoices and inventories in a readily retrievable manner. In addition, many records, including confidential prescription records, were stored in the pharmacy’s basement, which was not secure.

¹⁰ As discussed at hearing, Schedule II-V controlled substance prescriptions are valid for six months and may be authorized for up to five refills. See 657 IAC 10.28. Records of controlled substance prescriptions must be kept for two years from the last refill date.

***Count IV: Bauder Pharmacy and Mark Graziano
Failure to Properly Sign and Date Invoices for Controlled Substances***

657 IAC 8.9(1) requires all pharmacies to maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded. The invoices must be maintained for at least two years.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.9(1) by not maintaining all supplier invoices for a period of two years and by not ensuring that a pharmacist or other responsible individual signed the invoice to clearly record receipt of the controlled substances listed on the invoice.

***Count V: Bauder Pharmacy and Mark Graziano
Dispensing Schedule II Controlled Substances in Quantities Exceeding Prescriber
Authorization***

657 IAC 10.21(5) authorizes a pharmacist, after consultation with the prescriber or the prescriber's agent and documentation of such consultation, to change the drug strength, dosage form, or drug quantity on a Schedule II controlled substance prescription. During the March 16, 2012 pharmacy inspection, Jean Rhodes found a prescription for oxycontin 20mg/ml that was written for 10 ml. The manufacturer supplied the drug as a 30ml container and this is what the pharmacy dispensed, but there was no documentation that the prescriber authorized the change. Following the inspection, Mark Graziano corrected this deficiency by obtaining a corrected prescription from the prescriber. The Board concluded that this corrected deficiency involving one prescription does not merit finding a separate violation against Respondents.

***Count VI: Bauder Pharmacy and Mark Graziano
Failure to Comply with Requirements for Partial Filling***

657 IAC 10.23 is the Board's rule regulating partial filling of Schedule II controlled substances. If a pharmacy is unable to supply the full quantity called for in a prescription, the pharmacists may partially fill a prescription, so long as the pharmacist notes the quantity provided on the prescription record and the

remaining portion of the prescription is filled within 72 hours of the first partial filling. No further quantity may be supplied beyond 72 hours without a new prescription.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.23 when they partially filled Schedule II prescriptions and then filled the balance of the prescription more than 72 hours after the partial filling. This deficiency was specifically cited at the time of the March 16, 2012 inspection.

***Count VII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete and Accurate Perpetual Inventories of Schedule II
Controlled Substances***

657 IAC 10.33 requires all pharmacies that dispense Schedule II controlled substances to maintain a perpetual inventory system for all Schedule II controlled substances in accordance with the rule. The perpetual inventory must be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

The perpetual inventory may be maintained in a manual or electronic format. 657 IAC 10.33(1). The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by nation drug code (NDC) number. The record shall be updated to identify each prescription filled and each shipment received. 657 IAC 10.33(2). The pharmacist in charge shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the pharmacist in charge shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 10.16(124) and to the DEA pursuant to DEA regulations. 657 IAC 10.33(4).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.33 when they failed to maintain a complete and accurate perpetual inventory of Schedule II controlled substances. At the time of the March 16, 2012 inspection, the perpetual inventory for Schedule II controlled substances had multiple negative balances due to errors in the way the pharmacy was partially filling Schedule II controlled substances. When a Schedule II

prescription was partially filled, the actual amount dispensed should have been recorded. When the pharmacy dispensed the owed quantity on the prescription, there should have been a separate entry.

***Count VIII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete and Accurate Inventory of Controlled Substances***

All registrants are required to take an initial inventory of all stocks of controlled substances on hand on the date the registrant commences business and is thereafter required to take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within one year of the previous inventory date. 657 IAC 10.35(2),(3). Each inventory record must comply with the requirements of subrule 10.35 and must be maintained for a minimum of two years from the date of the inventory. 657 IAC 10.35(1). Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken. 657 IAC 10.35(1)(a).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.35 when they failed to maintain complete and accurate inventories of the Schedule III controlled substances. Respondents clearly were not maintaining accurate inventories when many hundreds of thousands of hydrocodone were missing from the pharmacy.

***Count IX: Bauder Pharmacy and Mark Graziano
Failure to Document Verification of Controlled Substance Refills***

657 IAC 21.5 requires the individual pharmacist who makes use of the pharmacy prescription application to provide documentation of the fact that the refill information entered into the pharmacy prescription application each time the pharmacist refills an original written, fax, or oral prescription order for a controlled substance is correct.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 21.5 when they failed to document verification of controlled substance refills for a period of two years. This deficiency was noted during the March 16, 2012 inspection and was cited in the March 22, 2012 inspection report. Mark Graziano admitted to Jean Rhodes that he did not

understand this requirement. He believed that his reports to the PMP provided sufficient documentation of verification.

***Count X: Bauder Pharmacy and Mark Graziano
Failure to Properly Supervise Dispensing Functions Delegated to Non-
Pharmacists***

This count cites 657 IAC 3.20, which states that the ultimate responsibility for the actions of a pharmacy technician shall remain with the supervising pharmacist. The Board was unable to find any evidence to support a separate violation under this count. The pharmacy and pharmacist in charge were responsible for the pharmacy technician's failure to have a current registration for more than two years, but this violation is addressed in Count XII.

***Count XI: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete Patient Records***

657 IAC 6.13(1) specifies the patient record system that must be maintained by all pharmacies. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for obtaining, recording, and maintaining the following information: a. known allergies;...g. [p]harmacist comments relevant to the individual's drug therapy, including (1) known drug reactions, ...(3) [k]nown chronic disease conditions or disease states of patients, (4) [t]he identity of other drugs, over-the-counter drugs, herbals, other alternative medications, ...that may relate to prospective drug review.

This count relates to the two shopper survey reports. One shopper reported that she was not asked for any patient history, current health conditions, medications or allergies when her new prescription was filled by Mark Graziano. The second shopper reported that she was asked about allergies but was not asked about disease states or other medications that she was taking. The shoppers did not testify at hearing and the record does not include the pharmacy's patient records for the two shoppers. The Board declined to find separate violations with respect to this count.

***Count XII: Bauder Pharmacy and Mark Graziano
Failure to Ensure All Pharmacy Technicians Have Current Registration***

657 IAC 3.11(2) provides that a pharmacy technician registration that is not renewed before its expiration date shall be delinquent, and the registrant shall not continue employment as a pharmacy technician until the registration is reactivated. An individual who continues employment as a pharmacy technician without a current registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue to practice as a pharmacy technician, may be subject to disciplinary sanctions. See also 657 IAC 36.1(4)(aa).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 3.11(2) and 36.1(4)(aa) when they permitted Jennifer Higgins to continue working as a pharmacy technician for nearly eighteen months after her pharmacy technician registration had expired.

***Count XIII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Policies and Procedures for the Operation of the Pharmacy***

657 IAC 6.2(14) provides that there must be one professionally competent, legally qualified pharmacist in charge of each pharmacy who is responsible for establishing and implementing policies and procedures for all operations of the pharmacy. The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 6.2(14) by failing to have adequate written policies and procedures for all operations of the pharmacy. It is the responsibility of the pharmacist in charge to establish and implement policies and procedures for all operations of the pharmacy. The March 22, 2012 inspection report and the credible testimony of Jean Rhodes establishes that there were only minimal policies and procedures for Bauder Pharmacy, mostly relating to interns, at the time of the March 16th inspection. The pharmacy did not even have interns at the time of the inspection. In addition, when Ms. Rhodes returned to Bauder Pharmacy on October 11, 2012, pharmacist in charge Kim Robertson was unable to provide the policies and procedures for the operation of the pharmacy.

***Count XIV: Bauder Pharmacy and Mark Graziano
Failure to Provide Proper Security for Prescription Medications and Pharmacy
Records Stored in Basement***

657 IAC 6.7 provides that while on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for the effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657-Chapter 21. The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site, except as provided in subrule 6.7(2). The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 6.7 when they stored prescription medications and confidential patient records in the pharmacy's basement, which was unlocked and not protected from unauthorized access.

***Count XV: Mark Graziano
Failure to Wear an Identification Badge***

657 IAC 8.4(4) requires pharmacists to wear a visible identification badge while on duty that clearly identifies the person as a pharmacist and includes at least the pharmacist's first name. The preponderance of the evidence established that Mark Graziano violated 657 IAC 8.4(4) when he repeatedly failed to wear an identification badge while working in the pharmacy.

***Count XV: Bauder Pharmacy and Count XVI: Mark Graziano
Failure to Have Required Policies, Procedures and Documentation for Pharmacy
Technician Training***

657 IAC 8.14 requires all Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons to develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Pharmacy technician and support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.14 when they failed to establish policies and procedures for the training and utilization of pharmacy technicians and failed to document pharmacy technician and support person training. This deficiency was documented in the March 22, 2012 inspection report and the credible testimony of Jean Rhodes. In addition, when Jean Rhodes returned to the pharmacy on October 11, 2012 to review the deficiency corrections with then pharmacist in charge Kim Robertson, the pharmacy still did not have a technician training policy.

***Count XVI: Bauder Pharmacy and Count XVII: Mark Graziano
Failure to Have a Continuous Quality Improvement Program***

657 IAC 8.26 requires all licensed pharmacies to implement and participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and quality of patient care.

The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of the rule.¹¹ Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel.¹²

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.26 by failing to have a written CQI program. This deficiency was documented in the March 22, 2012 inspection report and the credible testimony of Jean Rhodes. In addition, when Jean Rhodes returned to the pharmacy on October 11, 2012 to review the deficiency corrections with then pharmacist in charge Kim Robertson, the pharmacy still did not have a technician training policy.

¹¹ 657 IAC 8.26(2).

¹² 657 IAC 8.26(3).

***Count XVII: Bauder Pharmacy and Count XVIII: Mark Graziano
Failure to Meet Minimum Standards for Sterile Compounding***

“Sterile compounding” means the aseptic processing in a clean environment of any pharmaceutical preparations that are required to be sterile when they are administered into patient body cavities, central nervous and vascular systems, eyes and joints,..., including but not limited to injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions)...¹³ 657 IAC Chapter 13 is entitled “Sterile Compounding Practices” and establishes the standards and procedures for the preparation, labeling, and distribution of sterile preparations by licensed pharmacies pursuant to a practitioner’s order or prescription.¹⁴

657 IAC 13.3(1) provides that each pharmacy shall have a pharmacist responsible for ensuring that:

- a. Preparations are accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.
- b. Appropriate cleanliness conditions are maintained, including preservation of the sterile environment during the compounding process.
- c. Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen beyond-use date or, if a written standard is not available, a maximum 24-hour expiration shall be used.
- d. Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits.

Each pharmacy that performs sterile compounding is also required to have a written quality assurance procedure.¹⁵

657 IAC 13.3(3) provides that all personnel involved with compounding, repackaging, or manipulating sterile preparations shall be adequately educated

¹³ 657 IAC 13.2.

¹⁴ 657 IAC 13.1.

¹⁵ 657 IAC 13.3(2).

and trained. Training shall include written documentation certifying that the compounding personnel are able to adequately complete the activities listed in subsections "a" to "f."

657 IAC 13.6 requires pharmacies performing sterile compounding to have a written policy and procedure manual for the compounding, dispensing, delivery, administration, storage, and use of sterile preparations. The manual shall establish policies and procedures relating to subjects identified in this rule and other rules within 657 IAC chapter 13.

657 IAC 13.31 requires pharmacies to establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care.

Mark Graziano was the only pharmacist performing sterile compounding at Bauder Pharmacy. Mr. Graziano was responsible for developing all required policies and procedures for sterile compounding, including the development of a written quality assurance procedure. Mr. Graziano was also responsible for documenting that he was adequately educated and trained. The preponderance of the evidence established that Respondents Bauder Pharmacy and Mark Graziano violated 657 IAC 13.3, 13.3(2), 13.6, and 13.31 by failing to develop and implement written policies and procedures for sterile compounding, including failure to adopt a written quality assurance program. Bauder Pharmacy and Mark Graziano violated 657 IAC 13.3(3) by failing to document appropriate education, training, and proficiency of the pharmacy's compounding personnel.

657 IAC 13.7(2) relates to batch preparation and requires each container of a batch preparation compounded in anticipation of later dispensing to bear a label with at least the following information: name and quantity of all contents, internal code to identify the date and time of preparation and the preparer's and reviewing pharmacist's initials or unique identifiers, stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual, and auxiliary labels as needed.

The preponderance of the evidence established that at the time of the March 16, 2012 pharmacy inspection, the refrigerator in the sterile compounding area of Bauder Pharmacy had two unlabeled vials of HCG injectable, and there were no batch records for the product, in violation of 657 IAC 13.7(2).

657 IAC 13.11 establishes maximum storage periods for low-risk preparations. In the absence of the preparation passing a sterility test and provided the preparation is properly stored before administration, the storage periods shall not exceed 14 days at a cold temperature. 657 IAC 13.11(1)"d"(2).

The preponderance of the evidence established that Mark Graziano had assigned a 30 day beyond-use date to Lupron injections that were only permitted to have a 14 day beyond-use date.

657 IAC 13.25 requires the pharmacy to develop, maintain, and implement written procedures that include appropriate media-fill testing (MFT) by personnel authorized to compound preparations. Each person authorized to compound low-risk preparation shall annually perform a successful MFT procedure. 657 IAC 13.25(1).

The preponderance of the evidence established that Mark Graziano had never performed media-fill testing, in violation of 657 IAC 13.25. Mr. Graziano ordered a kit that was to be delivered in May 2012, but the pharmacy ceased performing sterile compounding after Mr. Graziano's pharmacist license was suspended, effective May 10, 2012.

657 IAC 13.27 requires, in part, that the primary engineering control device was to be placed in a buffer area with cleanable, nonshedding, smooth surfaces; all junctures shall be covered; and all cracks and crevices shall be caulked. 657 IAC 13.28 requires the pharmacy to have appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations.

The preponderance of the evidence established that several junctures in the buffer area needed recaulking and that peeling paint needed to be repaired, in violation of 657 IAC 13.27. The preponderance of the evidence further established that the pharmacy did not have written cleaning procedures or any documentation of cleaning, in violation of 657 IAC 13.28. Jean Rhodes was able to verify that these particular deficiencies had been corrected as of April 12, 2012.

657 IAC 13.29(1) requires all cleanrooms, laminar airflow workbenches, and barrier isolators to be certified by an independent contractor according to ISO Standards at least every six months. 657 IAC 13.29(2) requires the pharmacy to establish written procedures, appropriate to the risk level preparations

compounded by the pharmacy, which must include environmental testing, end testing, and evaluation of validation results. 657 IAC 13.29(2)(a) and (b) requires pharmacies to perform microbial air sampling and pressure differential monitoring.

The preponderance of the evidence established that Bauder Pharmacy only obtained certification of its clean rooms yearly, rather than every six months, in violation of the requirements of 657 IAC 13.29(1). The March 22, 2012 Inspection Report was the second notice on this violation. In addition, Bauder Pharmacy had never performed microbial sampling, had no pressure differential monitors, and had no procedures concerning environmental requirements. These deficiencies were not corrected by the pharmacy within 30 days.

***Count XVIII: Bauder Pharmacy and Count XIX: Mark Graziano
Failure to Provide Labeling and Record Keeping for Med Paks***

In lieu of dispensing prescribed drug products in conventional prescription containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized medication package (patient med pak) pursuant to the requirements of 657 IAC 22.5. A patient med pak is a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.¹⁶

The patient med pak shall be labeled as provided by 657 IAC 22.5(5), with the patient's name; a unique identification number for the patient and med pak and a separate identification number for each of the prescription drug orders for each of the drug products contained in the med-pak; the name, strength, dosage form, and total quantity of the drug; directions for use of each drug product; name of prescriber for each drug product; the date of preparation of the patient med-pak and the assigned beyond-use date; the name, address, and telephone number of the pharmacy; and the initials or unique identification of the responsible pharmacist.¹⁷ Pharmacies are also required to keep records of all med-paks.¹⁸

¹⁶ 657 IAC 22.5(1).

¹⁷ 657 IAC 22.5(5).

¹⁸ *Id.*

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 22.5 by failing to provide labeling and recordkeeping for the medpaks that it prepared for four customers.

***Count XIX: Bauder Pharmacy and Count XX: Mark Graziano
Failure to Provide Adequate Patient Counseling***

Patient counseling is required by Board rule.¹⁹ Pharmacists and pharmacies may be disciplined for attempting to circumvent patient counseling requirements or discouraging patients from receiving patient counseling concerning their prescription drug orders.²⁰ These counts were based on the shopper survey reports. Although the patient counseling reported by the two shoppers appeared to fall below Board expectations, the Board concluded that there was insufficient evidence to support separate findings of violation on these counts.

***Count XX: Bauder Pharmacy
Failing to Report Change in Pharmacist in Charge and Failing to Comply With
Requirements for Making the Change***

Iowa Code section 155A.19(1)(d) requires pharmacies to report to the Board, in writing, any change in the pharmacist in charge. 657 IAC 8.35(6)(c) requires a pharmacy to notify the Board, in writing, of a temporary pharmacist in charge within 10 days following a vacancy in the pharmacist in charge position. A permanent pharmacist in charge shall be identified within 90 days following the vacancy.

Effective May 10, 2012, the Board suspended the pharmacist license of Mark Graziano, who was the pharmacist in charge of Bauder Pharmacy. During a visit to the pharmacy on June 20, 2012, Compliance Officer Jean Rhodes had reminded Kim Robertson, R.Ph. that the pharmacy still had not identified a pharmacist in charge. The preponderance of the evidence established that Bauder Pharmacy violated Iowa Code section 155A.19(1)(d) and 657 8.35(6)(c) when it waited until July 23, 2012 to notify the Board that Kim Robertson was the new pharmacist in charge.

¹⁹ See 657 IAC 6.14.

²⁰ 657 IAC 36.1(4)(w).

Count XXI: Mark Graziano
Failing to Meet the Requirements for Practicing as Pharmacist in Charge

657 IAC 6.2 provides, in relevant part:

657-6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

...

6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

7. Delivering drugs to the patient or the patient's agent.

...

9. Training pharmacy technicians and pharmacy support persons.

10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

11. Distributing and disposing of drugs from the pharmacy.

12. Maintaining records of transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.

14. Establishing and implementing policies and procedures for all operations of the pharmacy.

15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices and controlled substances and to support the operations of the pharmacy.

The preponderance of the evidence established that Mark Graziano's performance as pharmacist in charge of Bauder Pharmacy was completely inadequate and failed to properly fulfill the above-listed responsibilities of the pharmacist in charge, in violation of 657 IAC 6.2.

***Count XXI: Bauder Pharmacy and Count XXII: Mark Graziano
Failing to Comply with Board Rules Regarding Manner of Issuance of
Prescription Drug or Medication Order***

657 IAC 8.19 specifies the manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in 657-21.9, or by electronic transmission in accordance with applicable federal and state laws, rules and regulations. Any prescription drug order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in 657-21.7.

A written, electronic, or facsimile prescription shall include: the date issued, the name and address of the patient, the name, strength, and quantity of the drug or device prescribed, the name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number, and the written or electronic signature of the prescriber.²¹

A prescription transmitted via facsimile shall include the identification number of the facsimile machine used to transmit the prescription to the pharmacy, the time and date of transmission, the name, address, telephone number and facsimile number of the pharmacy to which the prescription is being transmitted, and the manual signature of the prescriber if the prescription is for a controlled substance.²²

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano repeatedly violated 657 IAC 8.19. A review of 614 randomly selected prescriptions that were filled by the pharmacy between 2008 and 2012 revealed that only 166 of the prescriptions were legally correct. The remaining 448 prescriptions were incorrect or incomplete in one of the following respects:

- Sender's information cut off from fax;
- Wrong patient;
- Wrong prescriber;

²¹ 657 IAC 8.19(1)(a).

²² 657 IAC 8.19(1)(c).

- Wrong medication;
- No prescriber signature or verification;
- Wrong number of refills;
- Wrong directions;
- No prescriber DEA number for controlled substances;
- Faxed prescription not signed by prescriber;
- Wrong dispensed quantity;
- Filled beyond authorized time period;
- Filled prior to authorization;
- RX denied by prescriber but filled by pharmacy;
- No prescribed quantity;
- RX number not recorded on prescription;
- Dispensed generic when prescription indicated "Do not substitute."

***Count XXII: Bauder Pharmacy and Count XXIII: Mark Graziano
Failing to Comply with Board Rule Regarding Controlled Substance
Prescription Requirements***

657 IAC 10.21 provides that all prescriptions for controlled substances shall be dated as of, and signed on the date issued. Controlled substances prescriptions shall be valid for six months following the date of issue. A prescription for Schedule II, IV or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled.

657 IAC 10.21(1) *Form of prescription.* All prescriptions shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed and directions for use; and the name, address, and DEA registration number of the prescriber...A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

Androgel is an anabolic steroid that has also been placed in Schedule III.²³ The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano repeatedly violated 657 IAC 10.21 when Androgel was dispensed by the pharmacy without obtaining a legally correct prescription from a prescriber. The Androgel prescriptions reviewed by the Board's compliance officers including the following deficiencies:

²³ Iowa Code section 124.208(6)(be).

- No Dr. DEA number;
- No hardcopy in file;
- No prescriber signature;
- Stamped prescriber signature;
- Unauthorized refills dispensed;
- Refilled beyond 6 months;
- Initial file after prescription had expired (6 months);
- No patient name on hard copy prescription;
- No notation of verbal authorization;
- No RX number on prescription;
- Sender information cut off from fax;
- Wrong dosage form of medication;
- Filled prior to receipt of fax authorization.

***Count XXIII: Bauder Pharmacy and Count XXIV
Failing to Comply with Board Rules Regarding Faxed Prescriptions***

657 IAC 21.9 permits a pharmacist to dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. The faxed prescription drug order shall serve as the original prescription, shall be maintained for a minimum of two years from the date of last fill or refill, and shall contain all information required by Iowa Code section 155A.27, including the prescriber's signature or electronic signature. The faxed prescription drug order, if transmitted by the practitioner's agent, shall identify the transmitting agent by first and last names and title and shall include the prescriber's signature or electronic signature. A prescription for a controlled substance shall include the prescriber's manual signature. 657 IAC 21.3 addresses the pharmacist's responsibility to verify the authenticity of an electronically prepared or electronically or fax transmitted prescription.

The Board believes that Respondents' violations with respect to deficiencies in its faxed prescriptions have been adequately addressed under the prior two counts (Counts XXII and XXIII for Bauder Pharmacy and Counts XXIII and XXIV for Mark Graziano) The Board believes it is unnecessary to find additional violations under these counts.

***Count XXIV: Bauder Pharmacy and Count XXV: Mark Graziano
Failing to Comply with Board Rules Regarding Prescription Processing
Documentation***

657 IAC 6.8 requires all prescriptions to be dated and assigned a unique identification number that shall be recorded on the original prescription. The original prescription, whether transmitted orally, electronically, or in writing, shall be retained by the pharmacy. Refill documentation shall include date of refill and the initials or other unique identification of the pharmacist. Upon review of the record, the Board believes that the pharmacy had the required logs, although they were not signed by a pharmacist. The Board declines to find additional violations under these counts.

***Count XXV: Bauder Pharmacy and Count XXVI: Mark Graziano
Failing to Comply with Board Rules Regarding Record Retention Requirements***

657 IAC 8.9 provides that each inventory or other record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular record or inventory. Original hard copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department. The following records shall be maintained for at least two years.

8.9(1) Drug supplier invoices. All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded.

...

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.9 by failing to retain all drug supplier invoices for a minimum period of two years and by failing to record the date of receipt of controlled substances on all of the invoices.

***Count XXVI: Bauder Pharmacy and Count XXVII: Mark Graziano
Dispensing Controlled Substances Without a Prescription***

Iowa Code section 124.308(4) provides that except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance in Schedule III or IV, which is a prescription drug as determined under chapter 155A, shall not be dispensed without a written or oral prescription of a practitioner or without an electronic or facsimile prescription in accordance with subsection 5.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated Iowa Code section 124.308(4) by the repeated dispensing of large numbers hydrocodone tablets without a proper prescription. The factual basis for this violation was fully discussed in connection with Count I. In addition, Respondents violated Iowa Code section 124.308(4) when Androlog was repeatedly dispensed without a valid prescription. The Board declined to find a violation under this count with respect to the prescriptions filled at Bauder Pharmacy for CG.

Sanctions

The Board may consider the following factors in determining the nature and severity of disciplinary sanctions: the relative seriousness of the violation as it relates to assuring citizens of this state a high standard of professional care, the facts of the particular violation, any extenuating circumstances or other countervailing considerations, the number of prior violations or complaints, seriousness of prior violations or complaints, whether remedial action has been taken, and any other factors as may reflect upon the competency, ethical standards, and professional conduct of the licensee, registrant, or permittee.²⁴

The record includes a table summarizing prior cases where the Board has disciplined pharmacies and/or pharmacists for illegal diversion of or failure to properly account for controlled substances. (State Exhibit 77). The table provides minimal information about the particular facts of those cases. It is, however, abundantly clear to the Board that the violations in this case are far more egregious than these prior cases. This case involves far larger numbers of missing hydrocodone tablets as well as compelling evidence that the pharmacist in charge, who is also the majority owner of the pharmacy, was directly involved

²⁴ 657 IAC 36.1(3).

in the illegal distribution of the drugs. The violations established in this Decision and Order seriously threatened the public health, safety, and welfare.

In addition, a number of Respondents' other violations, including but not limited to the violations involving sterile compounding, also raise grave concerns for public health and safety. The Board's findings of violation in this case more than justify imposing the most severe disciplinary sanctions available to the Board, including permanent revocation of Mark Graziano's license to practice pharmacy and revocation of Bauder Pharmacy's controlled substance registration.

With respect to the pharmacy's controlled substance registration, it is true, as pointed out by the state, that the Order of Immediate Suspension and Order to Show Cause stated: **IF YOU DESIRE A HEARING REGARDING SUSPENSION AND POSSIBLE 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...IF RESPONDENT DOES NOT REQUEST HEARING IN THIS MATTER WITHIN THIRTY DAYS OF THE DATE OF THIS ORDER, RESPONDENT'S CONTROLLED SUBSTANCE REGISTRATION WILL BE DEEMED REVOKED WITHOUT FURTHER ORDER OF THE BOARD.** (Emphasis original)

In its brief filed on the day of the hearing, the state asserted that Bauder Pharmacy's controlled substances registration has already been "deemed revoked" because Bauder Pharmacy did not file a request for hearing on the immediate suspension of its controlled substances registration. Respondent's counsel did not specifically respond to this argument at hearing.

A review of the Board's legal file does not reveal any specific written request from Bauder Pharmacy for a hearing on the issue of the immediate suspension of its controlled substances registration. Nevertheless, the Board notes that the initial Order Granting Motion for Continuance, which was issued by the Board on May 15, 2012, states:

On May 11, 2012, the Respondents, Bauder Pharmacy, Inc. and Mark E. Graziano, through attorneys Mark Weinhardt and George LaMarca, requested a continuance of the hearing on the statement of charges, emergency order, and order of immediate suspension and order to show cause against the Respondents, Bauder

Pharmacy, Inc. and Mark E. Graziano. Respondents have provided sufficient justification for its motion for continuance.

This continuance order could be interpreted as the Board's acknowledgement that Bauder Pharmacy, Inc. did request a hearing on the Order for Immediate Suspension and Order to Show Cause. For this reason, the Board has elected to consider and address the issue of Respondent's controlled substance registration in this Decision and Order, rather than "deeming" the controlled substance registration to have been revoked.

DECISION AND ORDER

IT IS THEREFORE ORDERED that pharmacist license number 16752, issued to Mark Graziano, is hereby PERMANENTLY REVOKED.

IT IS FURTHER ORDERED that controlled substance registration number 1100280, issued to Bauder Pharmacy, Inc., is hereby REVOKED.

IT IS FURTHER ORDERED that pharmacy license number 222, issued to Bauder Pharmacy, Inc., is hereby issued a CITATION and WARNING for the violations of Board statutes and rules established in this Decision and Order.

IT IS FURTHER ORDERED that pharmacy license number 222, issued to Bauder Pharmacy, Inc., is hereby placed on INDEFINITE PROBATION, subject to the following terms and conditions:

A. Respondent Bauder Pharmacy, Inc. shall pay a civil penalty in the amount of \$25,000. 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 thirty (30) days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

B. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, a written plan of action for correcting all remaining deficiencies identified in this Decision and Order.

C. Respondent Bauder Pharmacy, Inc. is hereby prohibited from performing any sterile compounding, unless otherwise ordered by the Board. The pharmacy shall not request permission to resume sterile compounding until such time as the pharmacist in charge can verify proper training of staff and the adoption of policies and procedures for sterile compounding in accordance with Board rules and approved by the Board.

D. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, policies and procedures for all operations of the pharmacy.

E. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, a Quality Control Improvement (CQI) plan.

F. Respondent Bauder Pharmacy, Inc. shall obtain Board approval for every pharmacist in charge of the pharmacy.

G. Mark Graziano shall be allowed no access to the pharmacy department or to prescription drugs within the pharmacy.

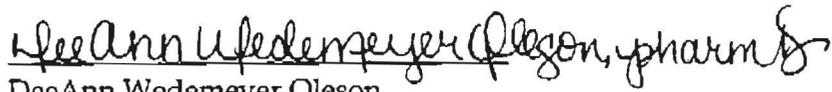
H. There shall be quarterly inspections of Bauder Pharmacy, Inc. to ensure full compliance with the rules governing pharmacy practice. Such inspections shall be conducted by a consultant approved by the Board, and shall be at the pharmacy's expense. The pharmacy shall comply with all recommendations made by the consultant. The pharmacy and the consultant shall submit quarterly reports to the Board. The reports shall be filed not later than March 5, June 5, September 5, and December 5 of each year of the indefinite probation.

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondents Mark Graziano and Bauder Pharmacy shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary/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 thirty (30) days of receipt of the bill.

Case No. 2012-52

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Dated this 5th day of April, 2013



DeeAnn Wedemeyer Oleson

Vice-Chairperson

Iowa Board of Pharmacy

cc: Theresa O'Connell Weeg, Assistant Attorney General
Rick Olson, Respondent's Attorney

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

IN THE MATTER OF:)	CASE NO: 2012-52
)	DIA NOS. 12PHB029
Pharmacy License of)	
BAUDER PHARMACY, INC.)	
License No. 222)	
Pharmacist License of)	FINDINGS OF FACT,
MARK GRAZIANO)	CONCLUSIONS OF LAW,
License No. 16752)	DECISION AND ORDER
)	
RESPONDENTS)	

On May 3, 2012, the Iowa Board of Pharmacy (Board):

- found probable cause to file Statements of Charges against Bauder Pharmacy, Inc. and Mark Graziano (Respondents);
- issued an Order of Immediate Suspension and Order to Show Cause that immediately suspended the controlled substances registration (number 1100280) issued to Bauder Pharmacy Inc.; and
- issued an Emergency Adjudicative Order indefinitely suspending the pharmacist license of Mark Graziano.

These documents were personally served on Respondents Bauder Pharmacy, Inc. and Mark Graziano on May 10, 2012. A June 26, 2012 hearing was initially scheduled on the Emergency Adjudicative Order and Statement of Charges issued to Mark Graziano. The hearing was continued four times at Respondents' request.

On October 8, 2012, the state filed Motions to Amend the Statements of Charges and First Amended Statements of Charges against both Respondents. Respondents did resist the Motions to Amend the Statements of Charges, and the motions were granted on November 30, 2012. Prehearing conferences were held on January 30 and February 22, 2013.

The consolidated hearing was held on February 26 and 27, 2013 in the Board Conference Room, 400 SW 8th Street, Des Moines, Iowa. The following members

of the Board served as presiding officers for the hearing: DeeAnn Wedemeyer Oleson, Vice-Chairperson; James Miller; Edward McKenna; and LaDonna Gratias. Assistant Attorney General Theresa O'Connell Weeg represented the state. Respondents Bauder Pharmacy and Mark Graziano were represented by attorney Rick Olson. The hearing was open to the public at Respondents' request, in accordance with Iowa Code section 272C.6(1) and 657 IAC 35.19(10). Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was later instructed to prepare the Board's written Decision and Order, in conformance with their deliberations.

Following the issuance of the Board's decision on April 5, 2013, Respondents filed a Petition for Judicial Review in Polk County District Court. On September 16, 2013, the district court issued an Order Granting Limited Remand to the Board. The district court remanded the case for the Board to take additional evidence relating to how and when the Board came into possession of the so-called Blackbook, the content of the Blackbook, and whether the Blackbook was sufficient to satisfy the Board's requirements for policies and procedures. The district court ordered the Board on remand to review its April 5, 2013 decision to determine whether any amendments or modifications are needed to Findings of Fact numbers 5c, 6, 21, and 23 and Conclusions of Law related to Counts XIII, XV, XVI, or XXI.¹ The court further ordered the Board to determine whether any

¹ The Statement of Charges lists counts against Respondents Bauder Pharmacy and Mark Graziano separately; while some counts that apply to both Respondents have the same numerical designation, there are some counts that apply to both Respondents that have different numerical designations. The district court's order referenced page numbers from the April 5, 2013 decision for the applicable counts in the Conclusions of Law. For clarity, the counts identified in the remand order will be itemized here. Count XIII on p. 40 is a charge against both Respondents relating to failure to maintain policies and procedures for the operation of the pharmacy. Count XV on p. 41 relates to failure to have required policies, procedures and documentation for pharmacy technician training and is a charge against Respondent Bauder Pharmacy. That count as it relates to Respondent Graziano is Count XVI and is discussed in the same paragraph. The district court's order references Count XV on p. 42, but it is in fact Count XVI that appears on p. 42. Count XVI relates to both Respondents' failure to have a continuous quality improvement program. As this count relates to the black book that is the subject of the remand, the Board assumes that the district court's reference to Count XV on p. 42 is a typographical error. That position is supported by the fact that later in the remand order the district court refers to Count XVI as one of the counts to be reconsidered. Count XXI on p. 48 is a charge against Respondent Graziano only and relates to failing to meet the requirements for practicing as pharmacist in charge.

amendments or modifications are needed to the probationary terms described in the Decision and Order section of the April 5 decision.

On October 15, 2013, the Board conducted an evidentiary hearing limited to the remand order issued by the district court. The consolidated hearing was held in the Board Conference Room, 400 SW 8th Street, Des Moines, Iowa. The following members of the Board served as presiding officers for the hearing: Edward Maier, Chairperson; James Miller; Edward McKenna; and Judith Trumpy. Assistant Attorneys General Meghan Gavin and Laura Cathelyn represented the state. Respondents Bauder Pharmacy and Mark Graziano were represented by attorney Rick Olson. The hearing was open to the public at Respondents' request, in accordance with Iowa Code section 272C.6(1) and 657 IAC 35.19(10). Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was later instructed to prepare the Board's written Decision and Order, in conformance with their deliberations.

For the convenience of the parties and the district court, the amendments by the Board to its April 5, 2013 decision following the October 15, 2013 remand hearing will be identified in this decision by underlining the amended text in the Findings of Fact and Conclusions of Law sections. The Board made no changes to the Decision and Order section of its April 5, 2013 decision.

THE RECORD

The hearing record includes the testimony of Jean Rhodes, Sue Mears, Kirby Small, Lloyd Jessen, Jennifer Higgins, and Mark Graziano. The record also includes State Exhibits 1-77 and 79 and Respondent Exhibits D-N. A Protective Order was issued for all exhibits containing patient names, with the exceptions of Respondents' Exhibits L and M. The record also includes the following procedural motions and orders: Board Orders Granting Motions to Continue; Order Following Prehearing Conference; State and Respondent Witness and Exhibits Lists; State Motion to Strike Lloyd Jessen from Respondent's Witness List, Respondent Resistance, and Order Denying State's Request to Strike; Respondent's Objections to State Exhibits and Order Overruling Respondent's Objections; State Motion for Protective Order and Order Granting Protective Order; and State's Hearing Brief.

The hearing record also includes State Exhibits 1 through 4 and Respondent Exhibits A through F which were admitted at the remand hearing held on

October 15, 2013. Additionally, the record includes the testimony of Jean Rhodes, Debbie Jorgenson, Sue Mears, Lloyd Jessen at the October 15 remand hearing.

FINDINGS OF FACT

Licensure/Ownership/Staffing of Bauder Pharmacy

1. At all times material to this Decision and Order, Bauder Pharmacy, Inc. operated a licensed general pharmacy (license number 222) located at 3802 Ingersoll Avenue in Des Moines, Iowa. At all times material to this Decision and Order, Mark Graziano, R.Ph. was both the majority owner and the pharmacist in charge of Bauder Pharmacy. Mr. Graziano has been licensed to practice pharmacy (license number 16752) in the state of Iowa since 1986. (Jean Rhodes testimony; State Exhibits 1, 3, 5, 7)

2. Bauder Pharmacy is a small, independently owned retail pharmacy that also has a lunch counter and soda fountain. Mark Graziano owns 68% of Bauder Pharmacy; his sister, Kim Robertson, owns 20%; and his mother owns the remaining 12%. Kim Robertson is also an Iowa licensed pharmacist and was working full-time at Bauder Pharmacy at all times relevant to the Statements of Charges. Bauder Pharmacy also had the following employees:

- Jay Wangerin, R.Ph., who was working as a part-time pharmacist (approximately 12 hours a week);
- Jennifer Higgins, who was working as a full-time pharmacy technician (45 hours a week);
- Jolene Cavanaugh, who worked at the lunch counter, ordered over-the-counter products for the store, and handled customer billing; and
- Shannon McGuire, who worked in the soda fountain.

(Rhodes, Graziano, Higgins testimony; State Exhibits 11, 29-34)

Anonymous Complaint Re: Illegal Distribution of Hydrocodone

3. On September 28, 2011, the Board received an anonymous telephone complaint from a person who claimed that Mark Graziano was illegally distributing 5,000 to 10,000 hydrocodone pills a month from Bauder Pharmacy. According to the anonymous complainant, Mark Graziano handed the

hydrocodone bottles out the back door of the pharmacy to an individual who distributed them. The complainant stated that he was willing to submit a complaint form but hoped to remain anonymous because Mark Graziano had threatened him with "guys from out of state" if he spilled the beans. The complainant also claimed that Mark Graziano had him hooked on hydrocodone, but that he was now trying to get clean. (State Exhibit 8) The Board did not hear from the complainant again until May 11, 2012. (State Exhibit 35)

Shopper Surveys of Bauder Pharmacy

4. In March 2012, inspectors from the National Association of Boards of Pharmacy conducted two "shopper surveys" at Bauder Pharmacy. Both inspectors presented themselves to the pharmacy as new customers with new prescriptions. Both inspectors completed an Iowa Pharmacy Shopper Survey Reporting Form that describe a number of deficiencies in their "shopper" experience. (Rhodes testimony; State Exhibits 7, 9, 10)

a. There were two pharmacists on duty during the March 8, 2012 shopper survey conducted by inspector Cheryl Anderson, R.Ph. Ms. Anderson only had contact with one of the pharmacists, who she was later able to identify as Mark Graziano. Ms. Anderson initially gave her prescription to a female employee who was not wearing a name tag. The employee did not ask Ms. Anderson for any of her health history, current health conditions, medications, or allergies. Mr. Graziano asked Anderson for her date of birth and address. In her report, Ms. Anderson notes that Mr. Graziano appeared more focused on a man who had entered the pharmacy while her prescription was being filled. The man did not stop at the drop-off or pick-up counter but walked directly to the rear of the pharmacy.

Ms. Anderson's prescription was ready in less than 10 minutes. The female employee took Anderson's payment and asked Mr. Graziano if Anderson needed to know anything. Mr. Graziano told the employee "take in AM." When the employee looked puzzled, Mr. Graziano said "Cheryl, take in AM" and then walked to the rear of the pharmacy. Ms. Anderson was not provided any counseling literature or monograph with the prescription. Mr. Graziano did not counsel Ms. Anderson on any of the medication's possible side effects, which included increased urination, decrease in blood pressure, and dizziness. The prescription given to Anderson was mislabeled. The label read: "Triamterene-HCTZ 37.5-2#15, but the drug strength for the HCTZ was 25 mg not 2 mg. In

addition, the prescription bottle had an easy open lid that was not requested or authorized by Ms. Anderson. (State Exhibit 9)

b. A female in a white lab coat waited on secret shopper Denise Frank at the time of the March 14, 2012 survey. The female employee was not wearing a name tag and did not identify herself to Ms. Frank as a pharmacist. The employee asked Ms. Frank about allergies but did not ask about her disease states or any other medications that she was taking. Ms. Frank noted in her report that it would have been prudent of the pharmacist to ask her about her OTC medications in order to prevent duplicate therapy because the prescription medication was also available over-the-counter.

Ms. Frank also noted that there were no privacy panels for the counseling area. A customer was standing directly behind her while the female waited on her and customers at the fountain counter could hear everything being said. The prescription was ready in eight minutes, and the female employee spoke to Ms. Frank as she rang up the order. The employee told Frank to avoid caffeine and spicy foods and added "it's 1 twice a day." The prescription was put in a non-child proof container that Ms. Frank did not request. (State Exhibit 10)

March 16, 2012 Pharmacy Inspection

5. Jean Rhodes, R.Ph. has been a pharmacist for 14 years and has been employed by the Board as a Compliance Officer for 8½ years. On March 16, 2012, Ms. Rhodes was assigned to conduct a pharmacy inspection of Bauder Pharmacy and to prepare an inspection report. This inspection was prompted by the anonymous complaint and by the results of the shopper surveys. Ms. Rhodes was assisted by Sue Mears, R.Ph., who was a new compliance officer in training. (Rhodes, Mears testimony)

Bauder Pharmacy's last inspection had been conducted on July 24, 2008.² Ms. Rhodes explained the time gap between the two inspections. There is a backlog of routine pharmacy inspections, and the four year gap between inspections at Bauder Pharmacy is not that unusual. Some pharmacies have not had an

² The July 2008 inspection included an audit of Schedule II controlled substances but did not include an audit of Schedule III or IV controlled substances. The inspection report only included a count of the Schedule III and IV inventory on hand. A total of 3000 tablets of all dosages of hydrocodone APAP were on hand in the pharmacy at the time of the 2008 audit. (Respondent Exhibit N)

inspection in 5 or 6 years. The Board's Compliance Officers are assigned to specific territories, and they give first priority to complaint investigations. If there is a need for a complaint investigation, the Compliance Officer will usually conduct a routine inspection at the same time. (Rhodes testimony; State Exhibits 7, 11; Respondent Exhibit N)

a. The Pharmacy Inspection Report was issued by Jean Rhodes on March 22, 2012. The report notes that Bauder Pharmacy maintains the following hours: Monday-Friday 8:30-6:00, Saturdays 9:00-3:00, Sundays 10:00-12:00, and Holidays, 10:00-12:00. The retail store and lunch counter are only open when the pharmacy is also open because the pharmacy dispensing area cannot be separately locked. At the time of the March 16th inspection, the pharmacy was performing sterile compounding of two medications (Lupron and HCG). The counseling area was limited. The pharmacy specialized in fertility medications, and fertility counseling was encouraged before and after business hours to promote confidentiality. (State Exhibit 11, pp. 57-58)³

b. During the March 16th inspection, the Board's Compliance Officers reviewed the pharmacy's Schedule II Controlled Substance Perpetual Inventory, its annual inventory (last performed May 3, 2011), and hard-copies of prescriptions, invoices, and executed DEA 222 forms. The Compliance Officers did not perform a controlled substances audit during the March 16th inspection. (State Exhibit 11, pp. 57-58)

c. The Inspection Report describes the following areas of non-compliance requiring correction:

- **Registration renewal.** Pharmacy technician Jennifer Higgins' registration had expired on September 30, 2010 and had not been renewed. See 657 IAC 3.11(2). Ms. Higgins submitted her renewal application to the Board on March 20, 2012.
- **Pharmacist in charge.** The pharmacy had minimal policies and procedures, which are the responsibility of the pharmacist in charge. See 657 IAC 6.2(14). The Compliance Officers provided pharmacist Kim Robertson with a guideline handout for policies and procedures.
- **Security.** Outdated medications, including controlled substances, and patient records were not effectively secured against theft, diversion or

³ The page numbers provided in the Decision and Order refer to the consecutive pagination throughout the state's exhibit book which is found in the lower right hand corner of each page.

unauthorized access. See 657 IAC 6.7, 657 IAC chapter 21. Outdated medications and patient records were stored in the basement, which could be accessed by any store personnel or by delivery drivers because the back door is adjacent to the basement stairs. This was the second notice concerning the pharmacy's storage of outdated drugs, and Mark Graziano was told to contact his reverse distributor for disposal of the drugs.

- **Identification badge.** Although visible name badges are required for pharmacists by Board rule, Pharmacist Mark Graziano admitted that he seldom wears a name badge because his customers all know him. This was the second notice on this violation. See 657 IAC 8.4(4).
- **Drug supplier invoices.** The pharmacy's controlled substance invoices needed to be signed and dated when received by the pharmacist or other responsible individual. 657 IAC 6.9(1).
- **Training and utilization of pharmacy technicians and pharmacy support.** The pharmacy did not have a written policy for training of pharmacy technicians and pharmacy support persons and did not document training. See 657 IAC 8.14.
- **Continuous quality improvement program(CQI).** The pharmacy did not have the required written CQI program, which is required to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate and prevent medication errors. Pharmacists Mark Graziano and Kim Robertson were able to explain their processes for a dispensing error. Mr. Graziano estimated that the pharmacy had about one error a week, while Ms. Robertson thought errors rarely happened. See 657 IAC 8.26.
- **Schedule II prescriptions.** RX 673021 was written for Oxy 20mg/ml, 10 ml, but the manufacturer supplies a 30ml container. The pharmacy had dispensed a 30ml container without documenting that the pharmacist contacted the prescriber for authorization to change the prescribed quantity. See 657 IAC 10.21(5).
- **Schedule II prescriptions-partial filling.** If the pharmacist is unable to supply the full quantity of Schedule II controlled substance prescription, the pharmacist may partially fill the prescription and make a notation on the record as long as the remaining portion of the prescription is filled within 72 hours. If the remaining portion of the prescription can't be filled within the 72 hours then the prescriber must be notified and a new prescription must be obtained. The pharmacy was partially filling Schedule II prescriptions and supplying the balance of the prescription

beyond the 72 hour limit, resulting in several negative balances on the Schedule II perpetual log. See 657 IAC 10.23.

- **Information included.** The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug or by national drug code number. The record shall be updated to identify each prescription filled and each shipment received. The pharmacy had multiple negative balances in the Schedule II perpetual inventory. See 657 IAC 10.33(2).
- **Schedule I and II records.** Inventories and records of controlled substances listed on Schedule I and II must be maintained separately from all other records. The pharmacy kept its Schedule II invoices with its Schedule III-V invoices. See 657 IAC 10.34(1).
- **Ordering or distributing Schedule I or II controlled substances-electronic ordering system.** When a pharmacy receives a shipment of Schedule I or II drugs, it is required to create a record of the quantity of each item and the date received and then electronically link it to the original order and identify the individual reconciling the order. The pharmacy had never electronically linked the receipt of Schedule I and II drugs for a wholesaler. During the inspection, Mr. Graziano called the wholesaler's help line and was instructed on the procedure. See 657 IAC 10.34(7).
- **Record and procedure.** Each inventory shall contain a complete and accurate record of all controlled substances on hand at the date and time inventory is taken. The pharmacy's annual inventory on 5/3/11 had no value for hydrocodone/APAP 2.5/500mg. If there is no drug, the entry should have been zero. Pharmacist Robertson believed they had copied the drug list from the previous year but had no 2.5/500 mg on hand as it is seldom used. See 657 IAC 10.35(1).
- **Newly controlled substances.** Carisoprodol became a Schedule IV drug on 1/12/12 but had not been inventoried as required by Board rule. See 657 IAC 10.35(8).
- **Sterile compounding.** Mark Graziano was the only pharmacist who prepared sterile compounded products. The following deficiencies were noted with respect to sterile compounding:
 - ✓ The pharmacy had a hood that was inspected yearly rather than every 6 months as required;
 - ✓ The pharmacy lacked a written quality assurance (QA) procedure and lacked written policies and procedures for sterile compounding. 657 IAC 13.3(2), 13.6, 13.31;

- ✓ The pharmacy lacked documentation of the training and proficiency of its personnel involved with sterile compounding. 657 IAC 13.3(3);
 - ✓ The refrigerator had two unlabeled vials of HCG injectable. There were no batch records and no labeling of the product. 657 IAC 13.7(2);
 - ✓ Lupron injections were assigned a 30 day beyond-use date but are only permitted to have a 14 day beyond use date. 657 IAC 13.7(11);
 - ✓ Media fill testing was required annually but had never been done. 657 IAC 13.25;
 - ✓ There was peeling paint and areas that needed caulking in the buffer area where the primary engineering control device was located. 657 IAC 13.27(2);
 - ✓ There was no written cleaning procedures and no documentation of cleaning. 657 IAC 13.28;
 - ✓ All cleanrooms, laminar airflow workbenches, and barrier isolators are required to be certified every six months or whenever the device or room is relocated or altered or whenever major service to the facility is performed. Certification had only been done annually. 657 IAC 13.29.
 - ✓ Microbial sampling had never been done, there were no pressure differential monitors, and there were no procedures concerning environmental requirements. 657 IAC 13.29.
-
- **Verification of controlled substance refills.** The pharmacy had not verified controlled substance refills through a daily printout or logbook for the prior two years. Mark Graziano mistakenly believed that the Patient Monitoring Program (PMP) fulfilled this requirement. 657 IAC 21.25.
 - **Patient med paks.** The pharmacy was preparing med paks for four customers with no labeling or recordkeeping for the med paks. Pharmacist Kim Robertson stated that she planned to discontinue providing med paks. 657 IAC 22.5.
 - **Poison Prevention Packaging Act of 1970(PPPA), 15 U.S.C. §§ 1471-1476.** This Act requires pharmacies to dispense oral prescription drugs in special packaging unless the drug is exempt or the patient or prescribing practitioner requests nonspecial packaging. The majority of prescriptions were filled at Bauder Pharmacy using snap caps/easy off caps without documentation that the customer requested them. Pharmacist Robertson planned to contact customers to obtain signatures from those who want easy off caps. In addition, some of the pharmacy's customers brought in empty prescription vials for re-use, which also violates PPPA. Pharmacist Robertson agreed to stop this practice.

Bauder Pharmacy was required to correct these deficiencies and acknowledge the corrections to the Compliance Officer within 30 days of receipt of the inspection report. (Rhodes testimony; State Exhibit 11)

6. On April 12, 2012, Jean Rhodes met with Mark Graziano at the Board office to review Bauder Pharmacy's deficiency corrections. Although this type of review is usually conducted at the pharmacy, Mr. Graziano specifically asked to meet Ms. Rhodes at the Board's office. Ms. Rhodes made handwritten notes of their discussion on a copy of the inspection report (State Exhibit 71). Addendum #4 to Rhodes inspection report (State Exhibit 70) includes check marks for those items that Mark Graziano reported as corrected.

Ms. Rhodes notes from the meeting indicate, in part, that: the pharmacy technician's registration had been renewed, the unsecured outdated medications had been sent to a reverse distributor, someone was coming to destroy unsecured records stored in the basement, the pharmacist was wearing a name badge, the controlled substances invoices had been signed and dated, there was a technician training policy and documentation of training, Schedule II invoices had been separated from Schedule III-V invoices, verification of control substance refills had been documented, and the pharmacy had started a signature log for dispensing medications in non-child proof containers. (Rhodes testimony; State Exhibits 70-71)

Only a few of the deficiencies in the sterile compounding area were reported as corrected. Media fill testing, microbial sampling, and pressure differential monitors were expected to be addressed in May. There were still no policies and procedures for sterile compounding. (Rhodes testimony; State Exhibits 70-71)

At hearing, Jean Rhodes explained the critical importance of the sterile compounding regulations to public health and safety. A company in Massachusetts had recently been cited for significant violations of sterile compounding regulations that resulted in patient illnesses and deaths. The Board's sterile compounding regulations provide a means to verify that pharmacies have a safe sterile compounding environment and to ensure that there are no microbes in the air that could contaminate the compounded product and potentially cause patient infection or death. In addition, pharmacies must also document that they have established proper policies, procedures, and training specific to sterile compounding. (Rhodes testimony)

Audit of ARCOS and PMP Records from 1/1/08-3/21/12 [First Audit]

7. Following the March 16th inspection, Compliance Officers Jean Rhodes and Sue Mears decided to audit the hydrocodone and oxycodone⁴ medications purchased and dispensed by Bauder Pharmacy from January 1, 2008 through March 21, 2012. For this audit, Rhodes and Mears reviewed records of drug orders maintained on the federal Automation of Reports and Consolidated Order System (ARCOS) and dispensing records maintained on the state Prescription Monitoring Program (PMP). (Rhodes testimony; State Exhibit 7, pp. 46, 49-50; State Exhibits 12-27)

- ARCOS is a database collected by the U.S. Department of Justice Drug Enforcement Administration (DEA), Office of Diversion Control. Drug manufacturers and wholesalers are required to report all orders of Schedule I and Schedule II controlled substances and all narcotic controlled substances in Schedule III to ARCOS. Manufacturers and wholesalers report the ordering pharmacy's DEA number, a transaction date, and the trade name, drug code, quantity, dosage unit, dosage form, and national drug code for each drug that is ordered. (Rhodes, Jessen testimony; State Exhibits 18, 19)
- The Prescription Monitoring Program (PMP) was created by the Iowa legislature in 2009 to establish a central database of controlled substance prescriptions dispensed to patients in Iowa. At least twice a month, pharmacies must report all dispensing of Schedule II, III, and IV controlled substances to the PMP. The information reported must include the pharmacy's DEA number, the date that the prescription was filled, the prescription number, if the prescription is new or a refill, the NDC number for the drug, the quantity of the drug, the number of days of drug therapy provided by the drug as dispensed, patient information, the prescriber DEA number, the date the prescription was issued by the prescriber, and method of payment. (Rhodes testimony; See Iowa Code chapter 124.551-124.558; 657 IAC Chapter 37)

8. The results of the first audit are summarized in State's Exhibits 7 and 12. This audit revealed that for the period from January 1, 2008 to March 12, 2012:

⁴ Hydrocodone is a narcotic that is a Schedule III controlled substance. Oxycodone is a Schedule II controlled substance. (Rhodes testimony; See Iowa Code sections 124.206, 124.208)

- ARCOS records indicate that Bauder Pharmacy ordered and received a total of 1,098,900 hydrocodone APAP tablets (all brands, all strengths). The majority of the hydrocodone products were one strength, hydrocodone APAP 7.5/500 (593,700 tablets);
- PMP records indicate that Bauder Pharmacy dispensed 358,012 hydrocodone APAP tablets (all brands, all strengths) to customers;
- A total of 740,888 hydrocodone APAP tablets that were ordered from wholesalers could not be accounted for through Bauder Pharmacy's PMP dispensing reports. The vast majority of the unaccounted for hydrocodone products (530,336) were hydrocodone APAP 7.5mg/500mg.

The audit also broke down the number of unaccounted for hydrocodone APAP tablets by calendar year, as follows:

- Calendar Year 2008: 229,846 tablets;
- Calendar Year 2009: 163,185 tablets;
- Calendar Year 2010: 155,436 tablets;
- Calendar Year 2011: 182,732 tablets;
- January-March 2012: 9,689 tablets

The compliance officers also created spreadsheets and graphs showing monthly totals for all hydrocodone and all oxycodone products, as well as breakdown totals for each type of product. Jean Rhodes spoke to DEA agent William Siegert who estimated that the higher strength tablets of hydrocodone (7.5mg and 10mg) had a street value ranging from \$10-\$20 a pill. (Rhodes testimony; State Exhibits 7, 12-27)

9. During the March 16, 2012 inspection of Bauder Pharmacy, pharmacist in charge Mark Graziano told Jean Rhodes that Bauder Pharmacy used the following 4 wholesalers: Anda, McKesson, H.D.Smith, and Dakota Drug. Mr. Graziano told Rhodes that he used four suppliers because of drug shortages. (Rhodes testimony; State Exhibit 7, p. 49)

When reviewing the ARCOS records for Bauder Pharmacy, however, the compliance officers observed that Bauder Pharmacy had used 14 different wholesalers to purchase hydrocodone products during the audit period. The compliance officers also observed that Bauder Pharmacy had ordered Hydrocodone APAP 7.5/500mg from 5 different suppliers in 1 day on 1 occasion;

from 4 different suppliers in 1 day on 3 occasions; from 3 suppliers in 1 day on 18 occasions; and from 2 different suppliers in 1 day on 75 occasions. (Rhodes testimony; State Exhibit 7, pp. 49-50; Exhibit 16)

Compliance Officer Sue Mears contacted two of Bauder Pharmacy's wholesalers to determine if they had experienced shortages of hydrocodone products. Anda reported some shortages of 5/325 and 5/500 strengths of hydrocodone that past fall. A representative of Top RX did not report any shortages but told Mears that some manufacturers may be reducing production levels of products with 500mg of APAP because by 2014 the FDA will no longer allow these products on the market. The Top RX representative also told Mears that his company requires a pharmacy to submit a usage report for the prior 3 months when filling out an initial application. If the controlled substance dispensing exceeds 30% of prescription volume, Top RX will not sell any controlled drugs to the pharmacy. (State Exhibit 7, p. 50)

10. Pharmacies are required to maintain complete and accurate records of all purchases and all dispensing or disposal of controlled substances. The purchase records must show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The records of all controlled substances dispensed or otherwise disposed of must show the date of dispensing, the name and address of the person to whom or for whose use, and the kind and quantity of drugs dispensed.

Pharmacies are required to maintain all records of controlled substances for at least two years from the date of the transaction. Prescriptions for controlled substances are valid for six months following the date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following issue. Controlled substance prescriptions must be maintained for two years from the last date of refill.

Inventories and other records of Schedule III, IV, and V records shall be maintained either separately from all other records or in a form so that the required information is readily retrievable from the pharmacy's ordinary business records. (Rhodes testimony; See also Iowa Code sections 124.306, 155A.12(4); 657 IAC 10. 21, 10.34, 8.9)

Pharmacists Kim Robertson and Jay Wangerin and pharmacy technician Jennifer Higgins all confirmed that Bauder Pharmacy received invoices from wholesalers with the delivery of their prescription drug orders. Following delivery, the pharmacist is responsible for checking in the controlled substance order and for signing and dating the invoice to document the shipment that was received. Invoices must be maintained in the pharmacy's records for a minimum period of two years. Pharmacist Kim Robertson was responsible for checking in all Schedule II controlled substances at Bauder Pharmacy. Either Ms. Robertson or another pharmacist checked in all other controlled substances. Mr. Wangerin told Board investigators that if he checked in controlled substances he always initialed and dated the invoice. (Rhodes, Jessen, Higgins testimony; State Exhibits 29-32; 657 IAC 8.9(1))

At the time of the March 16, 2012 pharmacy inspection, Bauder Pharmacy had approximately twenty years of controlled substance records stored in boxes in an unsecured area of the basement. Jean Rhodes informed Mark Graziano that the Board required controlled substance records to be kept for two years although insurance companies may require records for a longer period of time. Mr. Graziano asked Rhodes if he could shred records that were more than two years old if he was only keeping them for the Board, and she told him that he could. The March 22, 2012 Inspection Report authored by Jean Rhodes states, in part: *"The basement is also an area of storage for pharmacy records. Recommended to destroy some of the very old records as the Board of pharmacy typically needs records for two years and insurance companies possibly for 10 years. Some records may be close to twenty years old that are stored in the basement."* (Rhodes, Mears testimony; State Exhibit 11, p. 58)

At hearing, Mark Graziano testified that the West Des Moines Lions Club shredded some of his old records on April 27, 2012. Mr. Graziano provided a receipt from the Lions Club showing that he paid \$200 for the "shred-it" on April 27, 2012. Mr. Graziano also testified that Jean Rhodes and/or the Board shredded his documents. This was not true. (Graziano, Rhodes testimony; Respondent Exhibit H)

Service of the Board's Statements of Charges, Orders, and Administrative Search Warrant

11. On May 3, 2012, the Board signed and issued an Order of Immediate Suspension and Order to Show Cause that immediately suspended Bauder

Pharmacy Inc.'s controlled substance registration (number 1100280). The Board also found probable cause to file a Statement of Charges against Bauder Pharmacy, Inc., which alleged nineteen violations of state statutes and the Board's rules. (State Exhibits 4, 6) Also on May 3, 2012, the Board issued an Emergency Order that immediately suspended the pharmacist license (number 16752) issued to Mark Graziano. The Board also issued a Statement of Charges against Mark Graziano, which alleged 20 violations of state statutes and the Board's rules. (State Exhibits 1, 2)

On May 10, 2012, Jean Rhodes personally served the immediate suspension orders and the statements of charges on Bauder Pharmacy, Inc. and Mark Graziano. An administrative search warrant was served at the same time. The Board's Executive Director, several of the Board's compliance officers, and Matthew Sauer of the Iowa Division of Criminal Investigation (DCI) Cyber Crime Unit accompanied Rhodes to Bauder Pharmacy on May 10, 2012. (Rhodes, Jessen testimony; State Exhibit 28)

Mr. Sauer made a forensic image of the pharmacy's computer. Board staff seized all of the pharmacy's controlled substance records from January 1, 2008 through May 10, 2012 and all controlled substance medications. Pharmacist Kim Robertson and pharmacy technician Jennifer Higgins assisted the Board's compliance officers in attempting to locate the controlled substance records and medications, which were located throughout the pharmacy and in the basement of the building. Jean Rhodes told the pharmacy's employees to contact the Board if they located any additional controlled substance records for the relevant time period. The seized records and medications have been stored by the Board in locked, secure storage since May 10, 2012. (Rhodes, Jessen testimony; State Exhibit 28, pp. 492-493)

On May 10, 2012, the Board's compliance officers interviewed all Bauder Pharmacy employees, except Mark Graziano. The employees provided signed and witnessed voluntary statements and their interviews were also video recorded. The only employees who reportedly handled controlled substances as part of their duties were full-time pharmacists Mark Graziano and Kim Robertson, part-time pharmacist Jay Wangerin, and pharmacy technician Jennifer Higgins.

The employees reported that either Mark Graziano or Kim Robertson ordered controlled substances from the wholesalers. Kim Robertson checked in all

Schedule II controlled substances. When asked how many wholesalers were used by the pharmacy to order controlled drugs, pharmacist Jay Wangerin identified 4 wholesalers and pharmacist Kim Robertson identified 3 wholesalers. (Rhodes testimony; State Exhibits 28, pp. 492-493; Exhibits 29-34)

Kirby Small Interviews and Testimony at Hearing

12. On May 11, 2012, Kirby Small called the Board office and identified himself as the person who had previously made the anonymous telephone complaint against Bauder Pharmacy. Jean Rhodes and Sue Mears interviewed Kirby Small that day, and he told them that he would be willing to testify. Ms. Rhodes took notes during this first interview. (State Exhibit 35) On May 15, 2012, Rhodes and Mears conducted a second interview of Kirby Small, which was video recorded. (State Exhibit 36)

During his two interviews, Kirby Small told the compliance officers that he was present many times when Mark Graziano would pass a box containing bottles of hydrocodone APAP 7.5/500mg out the pharmacy's back door to a person that Small initially identified only as the "General." [Later in his interview, Kirby Small confirmed the identity of the General as well as two other persons he claimed were involved in the distribution of the hydrocodone] Mr. Small told Rhodes and Mears that he believed Mark Graziano had been illegally distributing hydrocodone since at least since 2005. Small believed that Mark Graziano used the money to cover his gambling losses and to pay for expensive cars. (Rhodes, Small testimony; State Exhibits 35, 36)

Kirby Small told Rhodes and Mears that he had been using 15-20 hydrocodone tablets a day for years and would receive 100 hydrocodone tablets from the General every week. Small told them that prior to making his anonymous report, the General and Mark Graziano refused to give him any more hydrocodone because he was unable to pay them. Mr. Small reports that after the General cut him off, he confronted Mark Graziano in the Bauder Pharmacy parking lot and told Graziano that he "knew everything." When Mark Graziano responded by telling Small that he did not know what he was talking about, Small admits he "went crazy" and told Graziano that he would not be able to "keep doing this."

According to Mr. Small, Pharmacist Kim Robertson came out to the parking lot and told Mark he had a telephone call. After Mark went back inside the

pharmacy, Small told Kim that Mark was selling hydrocodone out the back door of the pharmacy and would "ruin you." Kim reportedly told Small "you need help." According to Mr. Small, Mark Graziano later called and threatened him with sending some "guys" over to his house. Mr. Small did not believe this threat, and no one ever came to his house. (Rhodes, Small testimony; State Exhibits 35, 36)

Kirby Small reported that he was forced to go "cold turkey" and stop taking hydrocodone after the General and Mark Graziano cut off his supply. He reports that he spent three days on the couch, "jonesing" and was unable to eat. After he was finally free of the drugs and felt better, Mr. Small realized how much the hydrocodone had damaged his life and how much it was hurting others. This motivated him to come forward and testify. (State Exhibits 35, 36; Small testimony)

During his interview, Kirby Small admitted that he was on criminal probation for a "Department of Human Services thing" at the time he confronted Mark Graziano. On cross-examination at hearing, Kirby Small admitted that he had been convicted of elderly abuse for misusing his father's money. Mr. Small believes that Mark Graziano or the General called his probation officer to report that he had been smoking marijuana. Mr. Small was arrested for a probation violation and sent to jail for 15 days. If his probation had been revoked, Mr. Small would have been required to serve a five year prison sentence. Mr. Small admits this is what prompted him to make the initial anonymous telephone call to the Board in late September, 2011. Kirby Small later identified himself as the anonymous complainant after seeing the news report on the Board's visit to the pharmacy and filing of charges. (Small testimony; State Exhibit 28, p. 494; Exhibits 35, 36)

At hearing, Kirby Small described what happened the times that he went with "the General" to Bauder Pharmacy to pick up the hydrocodone. Mr. Small testified that he and the General would be out for coffee on a Saturday morning, and the General would call Mark Graziano to arrange the pick-up. Mr. Small testified that the hydrocodone pick-up usually occurred after 9:00 a.m. because the UPS truck delivered the hydrocodone to the pharmacy at around 9:00 a.m. (Small testimony; State Exhibits 35, 36)

Kirby Small testified that on some occasions he drove around to the back of the pharmacy and waited outside while the General went in the back door of the

pharmacy to get the hydrocodone. Other times, he would drop the General off at the front of the pharmacy and then drive around to the back of the pharmacy to wait for him. The General would come out the pharmacy's back door with a box containing 2-3 white stock bottles of 7.5mg hydrocodone. The "General" removed the labels from the bottles and got rid of them. Small testified that after the pick-up, he sometimes helped the General count the pills. After one of the pill counting sessions, Mr. Small kept one of the pharmacy stock bottles as a "souvenir." He brought the stock bottle, which did not have any label on it, to his interview at the Board office and to the hearing.⁵ (Small testimony; State Exhibit 79)

Kirby Small was unclear on how many times he went with the General to Bauder Pharmacy for the hydrocodone pick up. Initially, he testified that he went with the General probably no more than 10 times but later clarified that he meant "at least" 10 times. Mr. Small testified that the General also picked up hydrocodone from Bauder Pharmacy on many other occasions without him. (Small testimony)

At hearing, Mark Graziano denied ever having anything to do with Kirby Small other than filling his prescriptions and allowing Small to do some painting at his home when Small was unable to pay his bill at the pharmacy. Mr. Graziano admitted that he and Kirby Small know some people in common, but denied illegally distributing hydrocodone and denied that he ever threatened Kirby Small. (Small, Graziano testimony)

***Bauder Pharmacy Audit Using Wholesaler Records and Computer Records
from 1/1/08-3/21/12 [Second Audit]***

13. After the administrative search warrant was executed, Jean Rhodes and Sue Mears conducted a second audit using the invoices subpoenaed from Bauder Pharmacy's wholesalers, the invoices seized from Bauder Pharmacy, and the actual controlled substance dispensing records from the pharmacy's computer. The results of the second audit are summarized in State Exhibit 28. The second audit revealed that for the period from January 1, 2008 to March 12, 2012:

⁵ In his statements and in testimony at hearing, Mr. Small sometimes described the 7.5mg hydrocodone stock bottles as containing 5000 tablets and sometimes described them as containing 500 tablets. The hearing record does not contain any documentation that Bauder Pharmacy ever received stock bottles containing 5000 tablets, but there are many records for stock bottles containing 500 tablets. The stock bottle provided by Mr. Small (State Exhibit 79) appeared consistent in size with a 500 tablet stock bottle.

- The wholesaler verified invoices show that Bauder Pharmacy ordered and received a total of 1,049,300 hydrocodone APAP tablets (all brands, all strengths). Of these, 495,311 tablets were hydrocodone APAP 7.5/500;
- PMP records indicate that Bauder Pharmacy dispensed 359,313 hydrocodone APAP tablets (all brands, all strengths) to customers;
- There were 689,987 hydrocodone APAP tablets that were ordered and shipped to Bauder Pharmacy by wholesalers that could not be accounted for through the pharmacy's computerized dispensing records.

(Rhodes testimony; State Exhibit 28, pp. 495-496)

14. Rhodes and Mears created detailed spreadsheets comparing and analyzing the information obtained in the two audits. State Exhibits 37-44 are spreadsheets that list every wholesaler invoice and indicate whether the invoice was reported to ARCOS, whether it was provided by the wholesaler in response to the Board subpoena, and whether the same invoice was found in the records maintained by Bauder Pharmacy. (Rhodes testimony; State Exhibits 37-55)

a) Auburn was the only wholesaler that was unable to provide invoices for the entire audit period because it only had invoices going back as far as November 4, 2009. Because of this, the second audit was unable to verify 33,500 hydrocodone tablets that Auburn reported to ARCOS as having been ordered by Bauder Pharmacy in 2008 and was unable to verify 33,000 hydrocodone tablets from 2009. These unverified tablets were not included in the second audit and resulted in a lower number of purchases than those that had been reported in ARCOS. (State Exhibit 28, p. 495; Rhodes testimony)

b) For calendar year 2008, wholesaler Masters Pharmaceutical provided five invoices in response to the Board's subpoena that it had not been previously reported to ARCOS. These invoices were for an additional 2000 tablets of hydrocodone APAP 5/500mg and 2000 tablets of 7.5/500mg. (State Exhibit 28, p. 495; State Exhibit 37, p. 519-520, 527-528).

c) For calendar year 2009, all of the wholesaler's invoices matched the orders reported to ARCOS with the exception of the invoices that Auburn had not retained. (State Exhibit 28, p. 495; Exhibit 38)

d) For calendar year 2010, wholesaler Dakota Drug provided an invoice for 1000 tablets of hydrocodone APAP 7.5/500mg that had not been reported to ARCOS. (State Exhibit 28, p. 495; Exhibit 39, pp. 585-586).

e) For calendar year 2011, the following drugs were reported to ARCOS but were later returned to the wholesalers by Bauder Pharmacy: 100 tablets hydrocodone APAP 10/325mg returned to Cardinal; 1000 tablets hydrocodone APAP 10/325mg returned to Top RX; and 1000 tablets hydrocodone APAP 7.5/500mg returned to Top RX. (State Exhibit 28, p. 495, Exhibit 40, pp. 597-598, 602).

f) For calendar year 2012, wholesaler Auburn provided two invoices in response to the Board's subpoena that had not been reported to ARCOS. These included an invoice for 2000 tablets of hydrocodone APAP 7.5/500mg and an invoice for 1000 tablets hydrocodone APAP 10/325mg. (State Exhibit 28, p. 496; Exhibit 41).

g) Bauder Pharmacy was missing 137 invoices for its purchases of 144,000 tablets of hydrocodone APAP 7.5/500mg product during calendar years 2010, 2011, and 2012. Bauder Pharmacy should have been able to provide these invoices because they fell within the two year period for retention of controlled substances records. (State Exhibit 28, p. 497).

h) Bauder Pharmacy was also missing its annual inventories of hydrocodone products. (State Exhibit 28, p. 496).

i) A total of 907 hydrocodone tablets that were documented as having been dispensed per Bauder Pharmacy's computer dispensing records had not been reported by Bauder Pharmacy to the PMP. (State Exhibit 28, p. 496)

(Rhodes testimony)

15. On June 20, 2012, Jean Rhodes and Sue Mears met with pharmacist Kim Robertson at Bauder Pharmacy. At this visit, Jean Rhodes reminded Ms. Robertson that the pharmacy still needed to identify a new pharmacist in charge. Rhodes and Mears showed Ms. Robertson the 2010 and 2011 invoices that she had signed and asked her if she could explain the large discrepancy between the amount of hydrocodone APAP 7.5/500mg that she was signing for each month and the small amount that the pharmacy was dispensing.

- In 2010, Kim Robertson signed invoices for receipt of a total of 62,500 tablets of hydrocodone APAP 7.5/500mg, but the pharmacy's records showed that only 14,949 tablets had been dispensed. This meant that 47,551 tablets were not accounted for;
- From January to September of 2011, Kim Robertson signed invoices for a total of 58,500 tablets of hydrocodone APAP 7.5/500mg, but the pharmacy's records showed that 7,532 tablets were dispensed. This meant that 50,968 tablets were not accounted for.

Kim Robertson denied that any drug diversion was going on at the pharmacy and told Rhodes that she would only order the hydrocodone if there were prescriptions for it. Ms. Robertson also questioned whether the computer records could be wrong and asked to see the invoices. (Rhodes testimony; Exhibit 28, p. 496-497; Exhibits 43-44)

Jean Rhodes also informed Kim Robertson that the pharmacy had a large number of missing invoices and that the annual inventories of hydrocodone products were also missing. Ms. Robertson replied that she was sure the inventories were in the yellow notebook or in the front of the perpetual CII log. Rhodes and Mears returned to the secure storage area where the Bauder Pharmacy records were being kept and reviewed the CII perpetual log and the yellow notebook. The hydrocodone inventories were not there. (Rhodes testimony; Exhibit 28, p. 496)

16. On July 23, 2012, Bauder Pharmacy submitted a pharmacist in charge (PIC) change naming Kim Robertson as the new PIC. (Rhodes testimony; State Exhibit 56, p. 753-754)

Review of Randomly Selected Prescriptions Filled by Bauder Pharmacy 2008-2012

17. Jean Rhodes and Sue Mears reviewed 614 randomly selected prescriptions that had been filled by Bauder Pharmacy between 2008 and 2012. Only 166 of the 614 prescriptions met all of the legal requirements for prescriptions. The various deficiencies on these prescriptions included:

- Sender's information cut off from fax;
- Wrong patient;

- Wrong prescriber;
- Wrong medication;
- No prescriber signature or verification;
- Wrong number of refills;
- Wrong directions;
- No prescriber DEA number for controlled substances;
- Faxed prescription not signed by prescriber;
- Wrong dispensed quantity;
- Filled beyond authorized time period;
- Filled prior to authorization;
- RX denied by prescriber but filled by pharmacy;
- No prescribed quantity;
- RX number not recorded on prescription;
- Dispensed generic when prescription indicated "Do not substitute."

(Rhodes testimony; State Exhibit 56, pp. 753-755; Exhibits 57-61)

18. Jean Rhodes and Sue Mears conducted a separate review of the Androgel prescriptions filled by Bauder Pharmacy after their invoice review revealed frequent purchases of Androgel by the pharmacy. Androgel (testosterone) is a Schedule III controlled substance. Rhodes and Mears reviewed a total of 95 Androgel prescriptions filled by Bauder Pharmacy between 2010 and 2012. Only 3 of the 95 prescriptions were found to be legally correct. The deficiencies on the Androgel prescriptions included:

- No Dr. DEA number;
- No hardcopy in file;
- No prescriber signature;
- Stamped prescriber signature;
- Unauthorized refills dispensed;
- Refilled beyond 6 months;
- Initial fill after the prescription had expired (6 months);
- No patient name on hard copy prescription;
- No notation of verbal authorization;
- No RX number on prescription;
- Sender information cut off from fax;
- Wrong dosage form of medication;
- Filled prior to receipt of fax authorization.

(Rhodes testimony; State Exhibit 56, pp. 755-756; State Exhibits 62-64)

19. Jean Rhodes and Sue Mears visited the physician offices for three patients who had Androgel prescriptions filled by Bauder Pharmacy between August 2009 and April 2012. The purpose of these visits was to verify the validity of the prescriptions.

a) Bauder Pharmacy filled 9 prescriptions for Androgel in the name of Patient #1 between January 25, 2010 and April 21, 2012. Patient #1's physician's office could only verify 4 of the prescriptions. Bauder Pharmacy had dispensed a total of 420 unauthorized 1% 5gm gel packets in the name of this patient.

b) Bauder Pharmacy filled 6 prescriptions for Androgel in the name of Patient #2 between January 20, 2010 and April 30, 2012. Patient #2's physician's office could only verify 3 of the prescriptions. Bauder Pharmacy had dispensed a total of 600 unauthorized 1% 5gm gel packets in the name of this patient.

c) Bauder Pharmacy filled 8 prescriptions for Androgel in the name of Patient #3 between August 15, 2009 and April 30, 2012. Patient #3's physician's office could only verify 5 of the prescriptions. Bauder Pharmacy had dispensed a total of 450 unauthorized 1% 5gm gel packets in the name of this patient.

(Rhodes testimony; State Exhibit 56, p. 756; State Exhibit 65)

Review of Prescriptions for CG

20. During the initial audit, Jean Rhodes noted that CG was the only patient receiving brand name Lortab (Hydrocodone and Acetaminophen 7.5/500mg) from Bauder Pharmacy, and there were several early refills. CG is a family member of Mark Graziano. Jean Rhodes contacted CG's physician's office in an attempt to verify if he had authorized the patient's Lortab prescriptions. She obtained statements from the physician's staff members but it is unclear if she ever spoke to CG's physician. Ms. Rhodes determined that since July 18, 2011, Bauder Pharmacy had filled 5 unauthorized prescriptions for CG and had provided an additional 8 unauthorized refills. (Rhodes testimony; State Exhibit 56, pp. 756-757; Exhibit 66-69)

At hearing, Respondents submitted a February 25, 2013 letter from CG's physician, in which he states that he first met CG in January 2009. According to

the letter, CG was on Alprazolom and hydrocodone when the physician first met her, still is, and has been as long as he has known her. (Respondent Exhibit L) Respondents also submitted a March 6, 2012 prescription written by the physician for CG for hydrocodone/acetaminophen 7.5/500. (Respondent Exhibit M)

At hearing, Mark Graziano testified that CG is usually accompanied to her doctor appointments by one of her four family members who are licensed pharmacists. Mr. Graziano further testified that it is not unusual for the physician to give direct verbal authorization for CG's prescriptions to one of the pharmacists in CG's family. (Graziano testimony)

Rhodes' Return to Bauder Pharmacy on October 11, 2012

21. On October 11, 2012, Jean Rhodes revisited Bauder Pharmacy and met with pharmacist in charge Kim Robertson to review the deficiency corrections from the March 22, 2012 Inspection Report. Mark Graziano was behind the pharmacy counter when Ms. Rhodes entered the store. Ms. Robertson denied that Mr. Graziano was performing any pharmacist duties and told Rhodes that he was helping with the billing.

Ms. Rhodes asked to see the pharmacy's policies and procedures manual. Ms. Robertson checked with Mr. Graziano and they both claimed that the Board had taken the policies and procedures with all of the other records. Mr. Graziano stated that the policies and procedures were in the back of a black book. Following the visit, Ms. Rhodes reviewed the records in the Board's possession. The only black book was the daily controlled substance refill log. She then notified Ms. Robertson that the Board does not have possession of the pharmacy's policies and procedure manual. (Rhodes testimony; State Exhibit 70, pp. 815-816)

While Ms. Rhodes informed Mr. Graziano during the October 11, 2012 visit that the Board did not have a black book with the pharmacy's policies and procedures, the Board did come into possession of the black binder purporting to be the pharmacy's policies and procedures manual at some point between May, 2012 and October, 2012.⁶ The documents in the binder do not satisfy the Board's

⁶ The parties disagree regarding how the Board came into possession of the black binder. Respondents argued at the remand hearing held on October 15, 2013 that the black binder containing policy documents was seized pursuant to the administrative search warrant that the Board

general regulations regarding policies and procedures that a pharmacy must put in place, nor do they satisfy more specific regulations that are required for pharmacies that are engaging in specialized processes such as sterile compounding or dispensing medication packs to patients.

The pharmacy still did not have a Continuous Quality Improvement (CQI) program at the time of Rhodes' revisit, nor did it have a documented technician training policy.⁷ Ms. Rhodes also needed to verify that no legend medications or pharmacy records were being stored in the unsecured basement. Mr. Graziano had previously reported that medications had been sent to a reverse distributor and that someone was coming to destroy records. Upon checking the basement, Ms. Rhodes found hardcopy prescriptions from 2007 and also found shelves of older medications. (Rhodes testimony; State Exhibit 70, pp. 815-816; Exhibits 71A, 72, 73)

Respondents' Evidence at Hearing

22. Pharmacy technician Jennifer Higgins has been employed by Bauder Pharmacy for eight years. Ms. Higgins testified that Kim Robertson was primarily responsible for checking in the shipments of controlled substances to

executed in May, 2012. The binder, however, is not listed in the log of documents that were seized pursuant to the warrant. (See Resp. Remand Exh. D). Likewise, Ms. Rhodes testified that she never saw the binder in the secure storage room in the Lucas State Office Building where all the seized materials were stored by the Board, despite at least one targeted search for the binder in that location. Debbie Jorgenson, administrative assistant for the Board, testified that the binder was given to her by either Mark Graziano or his attorney, Rick Olson, on October 8, 2012, a date on which Mr. Graziano and Mr. Olson were at the Board's offices for depositions. The binder contains no label identifying it as the pharmacy's policies and procedures manual. Ms. Jorgenson testified that she assumed that a staff member of the Board had directed Mr. Graziano or Mr. Olson to give her the binder to be stored with the case materials, therefore she did not alert any Board staff members to its presence. While the Board credits Ms. Jorgenson's testimony regarding the date and manner of the Board's acquisition of the binder, the time frame during which the Board acquired the binder is ultimately irrelevant as the documents in the binder do not satisfy the Board's regulations regarding required policies and procedures. (Jorgensen testimony; Resp. Remand Exh. D; State Remand Exh. 3)

⁷ While the black binder the Board discovered after the initial hearing contains documents that contain some items that are relevant to a CQI program, the documents do not articulate a CQI program that comports with the Board's regulations.

the pharmacy. If Ms. Higgins opened a tote from a wholesaler and saw controlled substances in it, she would give the shipment to Ms. Robertson. Ms. Higgins was working at Bauder Pharmacy when Jean Rhodes conducted the March 16, 2012 inspection. Ms. Higgins testified that she was present when Ms. Rhodes presented Kim Robertson with a "stack" of unsigned invoices that had been collected and told her to sign them. Ms. Higgins did not actually observe Ms. Robertson sign these invoices. (Higgins testimony)

Only a pharmacist could place an order for a controlled drug at Bauder Pharmacy. After the controlled substances were checked in, Ms. Higgins might help put Schedule III-V controlled substances on the shelf. She estimated that they usually had about 2-3 bottles of 7.5/500 mg hydrocodone on the shelf at one time. Ms. Higgins never observed anyone take a stock bottle of hydrocodone out the back door of the pharmacy. (Higgins testimony)

23. In his testimony at hearing, Mark Graziano admitted that at the time of the March 16, 2012 pharmacy inspection:

- Jennifer Higgins' pharmacy technician registration had been expired since September 30, 2010. Mr. Graziano testified that he did not realize it had expired but admitted that as the PIC he was responsible for Ms. Higgins;
- Bauder Pharmacy did not have written policies and procedures, which are the responsibility of the PIC;
- There were outdated medications that were in an unsecured location in the basement;
- He was not wearing his identification badge. Mr. Graziano testified that he did not think the ID badge was necessary because all of his customers know him;
- All of the pharmacy's invoices were not signed;
- The only documentation of pharmacy technician training was on a notecard;
- The pharmacy did not have a written Continuous Quality Improvement (CQI) program. Mr. Graziano further admitted that he did not even know that a CQI program was required;
- There were a number of deficiencies involving the pharmacy's sterile compounding, including violations of the rules requiring: policies and procedures, a quality assurance program, documentation of training, and environmental testing. Mr. Graziano testified that he had been doing sterile compounding for four years but was not familiar with the federal

rules for sterile compounding (USP 797) and had little knowledge of the Board's rules on sterile compounding.

(Graziano testimony)

24. Mark Graziano admits that as PIC, he was responsible for the security of the pharmacy and for establishing policies and taking steps to prevent illegal diversion of drugs. Mr. Graziano provided the following testimony concerning the pharmacy's process for ordering and receiving controlled drugs:

- Mr. Graziano ordered controlled substances for the pharmacy, although the other two pharmacists could also place orders. He placed orders in one of three ways: in response to a telephone solicitation by a wholesaler's sales representative, on-line through the wholesaler's website, and by telephone. The majority of orders were placed by phone;
- When orders were placed on-line through a website, the person placing the order had to enter a User ID and a password. Mr. Graziano had trouble remembering his User ID and passwords and kept them on a "cheat" sheet underneath his computer;
- The majority of the pharmacy's controlled substance purchases were linked to the VISA credit card issued in the name of Mark Graziano/Bauder Pharmacy. The credit card had a \$50,000 limit, but the monthly charges on it were sometimes as high as \$75,000; and
- The controlled substance orders were delivered by various carriers and would arrive in either a tote or a box with the invoice. Kim Robertson was primarily responsible for checking in the controlled substance orders and signing off on the invoice, although any pharmacist could check them in. The invoices were filed in the basement.

Mark Graziano denies ever illegally dispensing hydrocodone from Bauder Pharmacy without a prescription and denies all of the claims of illegal distribution of hydrocodone made by Kirby Small. Mr. Graziano testified that he did not know that any drugs were missing from the pharmacy prior to May 2012 and if he had known, he would have notified the Board and the DEA. (Graziano testimony)

When asked how he explained the hydrocodone that could not be accounted for through the pharmacy's records, Mr. Graziano testified that the Board "made him" shred his older records. Mr. Graziano testified that the missing invoices

were probably in the wrong box and likely were shredded in late April 2012. He suggests that the missing invoices would help exonerate him of the charges of illegally dispensing hydrocodone. (Graziano testimony)

Mark Graziano testified that there were occasions when it appeared to him that someone had tampered with the security tape on boxes delivered to the pharmacy. Mr. Graziano estimated that Bauder Pharmacy received boxes from wholesalers that appeared to have been tampered with on 10-20 occasions. Mr. Graziano further testified that when this happened he refused to accept the shipment and notified the manufacturer. Mr. Graziano never reported any tampering or missing drugs to the police or to the Board. (Graziano testimony)

Mark Graziano also testified that drug orders were sometimes shipped to Bauder Pharmacy in error. He submitted documentation of one incident that occurred in January 2013. Dakota Drug mistakenly sent a shipment of hydrocodone APAP TB 10/235 to Bauder Pharmacy, when the shipment was intended for a pharmacy in Mason City. Bauder Pharmacy immediately notified the Board and Dakota Drug of the error, and the shipment was returned. Mr. Graziano questioned how Dakota Drug would have reported the order to ARCOS if Bauder Pharmacy had not alerted the Board. (Respondent Exhibit F; Graziano testimony)

After this mistake was reported, Jean Rhodes contacted Dakota Drug to inquire if these types of errors were very common. The shipping supervisor advised Rhodes that packages must go through at least three people prior to shipment, but that there is always the possibility of human error. He was not aware of any statistics that the company kept on errors. (State Exhibit 75)

Mark Graziano further testified that someone has had unauthorized access to his VISA credit cards, and he believes that his credit cards may have been used by someone else to order hydrocodone from his wholesalers. Mr. Graziano provided three partial VISA credit card statements (May 2010, April 2011, and May 2012) issued in the name of Mark E. Graziano/Bauder Pharmacy. The three credit card statements all had different account numbers. Mr. Graziano testified that he had to open the new accounts because the old accounts had been "tampered with." (Graziano testimony)

Mark Graziano did not explain what caused him to believe that the credit card accounts had been tampered with, and he did not provide any other information concerning these accounts. Mr. Graziano admits that even after he believed that

his credit card accounts had been compromised, he never compared his billing statements to his invoices to check for improper charges. He testified that he just assumed that any charges on his credit cards from his drug wholesalers were legitimate. Mr. Graziano testified that he did not connect the compromise of his credit cards to the hydrocodone shortages until just a few days prior to hearing. At hearing, Mr. Graziano suggested that someone who worked at the pharmacy may have used his credit card to purchase controlled substances. (Graziano testimony)

CONCLUSIONS OF LAW

Board's Authority to Discipline Licensees and Registrants

The Board is authorized to discipline pharmacists and pharmacies for any violation of Iowa Code chapters 155A, 124 or any rule of the Board. Specifically, Iowa Code section 155A.15(2)(c) and (h) authorize the Board to impose discipline, including but not limited to revocation, if it finds that a *licensed pharmacy* has:

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

...

h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

Iowa Code section 124.304(1)(d) also authorizes the Board to suspend, revoke, or restrict a controlled substances registration, issued under section 124.303 to manufacture, distribute, or dispense a controlled substance, upon a finding that the registrant committed such acts as would render the registrant's registration under section 124.303 inconsistent with the public interest, as determined under that section. The Board may suspend any registration simultaneously with the institution of disciplinary proceedings under section 124.304 if it finds that there is an imminent danger to the public health and safety which warrants this action.⁸

⁸ Iowa Code section 123.305(2).

Iowa Code section 124.303(1) sets out the factors that the Board may consider in determining whether issuance of a controlled substance registration would be inconsistent with the public interest. The factors include, in relevant part: the registrant's maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels and the registrant's compliance with applicable state and local law.

Iowa Code section 155A.12(1), (4), and (5) authorize the Board to impose discipline, including revocation, on any *licensed pharmacist* who:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.
- ...
4. Failed to keep and maintain complete and accurate records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.
5. Violated any provision of the controlled substances Act or rules relating to that Act.

Iowa Code section 17A.18 and 657 IAC 35.30 authorize the Board to issue an Emergency Adjudicative Order taking immediate action to suspend a license or registration when necessary to prevent or avoid immediate danger to the public health, safety or welfare.

***Count I: Bauder Pharmacy and Mark Graziano
Failing To Maintain Effective Controls and Accountability Over Controlled
Substances***

Iowa Code section 124.402(1) (a) provides that it is unlawful for any person, subject to Division III (Regulation of the Manufacture, Distribution, and Dispensing of Controlled Substances), to distribute or dispense a controlled substance in violation of section 124.308. Iowa Code section 124.308(4) prohibits pharmacies from dispensing a controlled substance included in Schedule III or IV without a written or oral prescription of a practitioner or without an electronic or facsimile prescription in accordance with subsection 5. The prescription for a Schedule III Controlled Substance may not be filled or refilled more than six

months after its issue date and may not be refilled more than five times, unless renewed by the practitioner.

A substance is placed in Schedule III if it has a potential for abuse that is less than that of substances in Schedules I and II, if the substance has a currently accepted medical use in treatment, and if abuse of the substance may lead to moderate or low physical dependence or to high psychological dependence.⁹ Hydrocodone is a narcotic drug that has been placed in Schedule III.¹⁰

657 IAC 36.1(ac) authorizes the Board to discipline any licensee, registrant, or permittee who fails to create and maintain complete and accurate records as required by state or federal law, regulation or rule of the Board.

The preponderance of the evidence established that Respondent Bauder Pharmacy violated Iowa Code sections 155A.15(2)(c) and (h), 124.402(1), 124.308 and 657 IAC 36.1(4(ac) when it failed to maintain adequate control over and accountability for controlled substances by failing to keep and maintain all required records of controlled substances and by failing to prevent loss or diversion of controlled substances from the pharmacy.

The preponderance of the evidence established that Respondent Mark Graziano violated Iowa Code sections 155A.12(1),(4), and (5), 124.402(1), 124.308 and 657 IAC 36.1(4(ac) when he failed to maintain adequate control over and accountability for controlled substances by failing to keep and maintain all required records and by failing to prevent loss or diversion of controlled substances from the pharmacy. As the pharmacist in charge (PIC), Mark Graziano was responsible for maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs.¹¹ He was also responsible for establishing and maintaining effective controls against the theft or diversion of prescription drugs and for maintaining records for such drugs.¹²

The preponderance of credible evidence in the record established that Bauder Pharmacy is unable to account for over 650,000 tablets of hydrocodone it received during the period of time covered by the Board's two audits. Board

⁹ Iowa Code section 124.207.

¹⁰ Iowa Code section 124.208(5).

¹¹ 657 IAC 6.2(12).

¹² 657 IAC 6.2(13).

staff conducted painstaking and detailed audits to identify this large number of unaccounted for hydrocodone tablets. The two audits yielded very similar results when the missing invoices from wholesaler Auburn (those before November 4, 2009) are taken into account. The first audit indicated that Bauder Pharmacy could not account for 740,888 hydrocodone tablets, while the second audit indicated that Bauder Pharmacy could not account for 689,987 hydrocodone tablets. It is impossible to calculate a precise count of the missing hydrocodone, due in large part to Respondents' repeated failures to properly create and maintain accurate records for controlled substances. Nevertheless, overwhelming evidence established that a gross quantity of hydrocodone tablets have been illegally diverted from Bauder Pharmacy and/or were dispensed from the pharmacy in violation of Iowa Code chapters 124, 155A, and the Board's rules. The preponderance of the credible evidence in the record further established that pharmacist in charge Mark Graziano was involved in the illegal diversion of large quantities of hydrocodone from Bauder Pharmacy.

Mark Graziano testified that he "stands by" the accuracy of the controlled substance dispensing reports that he made to the PMP. In fact, the number of hydrocodone prescriptions recorded on Bauder Pharmacy's computer system for the period of the audit was quite close to the number of hydrocodone prescriptions reported by Bauder Pharmacy to the PMP. (358,012 v. 359,313 tablets dispensed).

The number of hydrocodone tablets that Bauder Pharmacy dispensed by prescription stands in stark contrast to the far larger numbers of hydrocodone that Bauder Pharmacy ordered from wholesalers over the same period (per ARCOS records-1,098,900 hydrocodone tablets; per wholesaler verified invoices-1,049,300 tablets). Mark Graziano does dispute the accuracy of the ARCOS records, however. Through the second audit examining the actual invoices, the Board's compliance officers did identify a few errors in the ARCOS reports (although the errors were reporting omissions.) Nevertheless, it is also clear that the number of reporting errors is likely very small in comparison to the number of transactions that wholesalers reported. Errors in the ARCOS reports cannot possibly account for the huge discrepancies between Bauder Pharmacy's hydrocodone orders and its dispensing records.

As the pharmacist in charge, Mark Graziano was responsible for ensuring that Bauder Pharmacy created and maintained all required controlled substance records. State statutes and Board rules require most of these records, including

invoices, to be kept for a minimum period of two years. The records are required to be organized and readily retrievable by an agent of the Board.

Mark Graziano made repeated claims throughout his testimony suggesting that either Jean Rhodes or the Board shredded his records, thereby undermining his ability to defend himself against these charges. This is completely untrue and unsupported by the record. When Jean Rhodes arrived at Bauder Pharmacy to conduct the inspection on March 16, 2012, the pharmacy's controlled substance records were neither organized nor readily retrievable. A large number of records, including confidential patient records and other records close to 20 years old, were improperly stored in an unsecured area of the pharmacy's basement. Ms. Rhodes reasonably advised Mr. Graziano that he should get rid of some of the older records, and her inspection report clearly states, in bold print, that insurance companies may require records for up to 10 years. There is no evidence that Ms. Rhodes or the Board destroyed any records or directed Mr. Graziano which records he should destroy. Mr. Graziano submitted his \$200 receipt from the West Des Moines Lion Clubs for shredding some of the records. Mr. Graziano is the person responsible if records were misfiled and destroyed because he failed to verify the contents of boxes that he gave to the shredder.

As the pharmacist in charge and the person primarily responsible for ordering the hydrocodone, Mark Graziano must have been known the enormous numbers of hydrocodone tablets that Bauder Pharmacy was ordering from wholesalers. Over the period of the audit, Mr. Graziano ordered hydrocodone from 14 different wholesalers and frequently ordered hydrocodone from multiple different wholesalers in a single day. It is obvious to the Board that this was a strategy employed by Mark Graziano to try to conceal the large numbers of hydrocodone that he was ordering. It is significant that when Jean Rhodes asked Mark Graziano how many wholesalers he used to order controlled substances, he reported using only 4 wholesalers. Bauder's two other pharmacists reported that the pharmacy used 3 or 4 wholesalers. The wholesaler records show, however, that Bauder Pharmacy had in fact ordered hydrocodone from 7 different wholesalers in the first three months of 2012. (State Exhibit 41) In 2011, Bauder Pharmacy ordered hydrocodone from 11 different wholesalers. (State Exhibit 40) In 2010, Bauder Pharmacy ordered hydrocodone from 8 different wholesalers. (State Exhibit 41)

Some hydrocodone shipments may have arrived at Bauder Pharmacy in boxes that were damaged or appeared to have been tampered with. Some controlled

substances may have been shipped to Bauder Pharmacy in error. The Board is convinced, however, that this would have constituted a very small percentage of the overall number of hydrocodone shipments to Bauder Pharmacy. Moreover, Mark Graziano and Bauder Pharmacy were responsible for ensuring that all controlled substance shipments received at the pharmacy were checked against invoices for accuracy before the invoices were signed and dated. This is an essential step in maintaining accurate records. Mark Graziano and Bauder Pharmacy were required to properly report and document any missing drugs or any return of drugs received in error.

In his testimony, Mark Graziano suggested that an unnamed employee could have had access to his user name and password and could have ordered hydrocodone from wholesalers using his credit card, which he reports was compromised three years in a row. This testimony was neither credible nor plausible. Mr. Graziano provided no evidence to show that his credit card had ever been used to make hydrocodone purchases that he did not authorize. If the Bauder Pharmacy credit card had been compromised as Mark Graziano claims, it is completely implausible that he, as a small business owner, would continue to pay credit card balances in the range of \$50,000 every month without ever checking his statements for errors or unauthorized charges. Finally, as the pharmacist in charge Mr. Graziano was responsible for ensuring that proper security controls were in place for the pharmacy. This includes taking reasonable steps to protect his user name, password, and the credit card he had authorized to be charged for hydrocodone purchases.

Although there were some inconsistencies in Kirby Small's statements and testimony, the Board ultimately determined that Mr. Small's statements and testimony about the illegal distribution of hydrocodone from Bauder Pharmacy were more reliable and more plausible than Mark Graziano's denials. Mr. Small initially reported Mark Graziano's illegal distribution of hydrocodone in an anonymous telephone call to the Board nearly six months before the Board's first audit that revealed the large numbers of missing hydrocodone tablets.

From his first contact with Board staff, Mr. Small readily admitted that he was a drug user who was addicted to hydrocodone. After the Board's charges were made public, Mr. Small came forward to the Board and identified himself and also named others allegedly involved in the illegal distribution. He admitted that he had a criminal record. Mr. Small had nothing to gain from going public with his report, and he risked possible retribution and prosecution. Mr. Small

has provided the only plausible explanation for what happened to the hundreds of thousands of hydrocodone tablets that Mark Graziano and Bauder Pharmacy cannot account for.

***Count II: Bauder Pharmacy and Mark Graziano
Inadequate Security and Failure to Establish Effective Controls Against
Diversion***

657 IAC 10.15 requires all registrants to provide effective controls and procedures to guard against theft and diversion of controlled substances. The rule sets forth a number of factors for the Board to consider when evaluating a registrant's security system. The factors with particular relevance to this case include: the adequacy of supervision over employees having access to controlled substances and storage areas, the extent of unsupervised public access to the facility, and the adequacy of the registrant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances. 657 IAC 10.15(2)"i,""j," and "m."

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.15 by failing to provide effective controls and procedures to guard against the theft and diversion of controlled substances. All of the reasons cited in connection with Count I also support a finding of violation under this count. Bauder Pharmacy's system for monitoring the receipt, distribution, and disposition of controlled substances was wholly inadequate. In addition, Respondents stored expired controlled drugs in an unlocked and unsecured area of the basement, which could potentially be accessed by unlicensed employees and the public.

***Count III: Bauder Pharmacy and Mark Graziano
Failure to Keep and Maintain Records Required by the Controlled Substances
Act***

Iowa Code section 124.306 provides that persons registered to manufacture, distribute, dispense or administer controlled substances under Iowa Code chapter 124 shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and such additional rules as may be issued by the Board. A practitioner who engages in dispensing any controlled substances to the practitioner's patients shall keep records of receipt and disbursements of such drugs, including dispensing or other

disposition, and information as to controlled substances stolen, lost, and destroyed. In every such case the records of controlled substance received shall show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all controlled substances dispensed or otherwise disposed of, shall show the date of dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were dispensed and the kind and quantity of drugs dispensed.

"Practitioner" is statutorily defined to include a pharmacy. Iowa Code section 124.101(26)(b).

Iowa Code section 124.306 further provides that every such record shall be kept for a period of two years from the date of the transaction recorded. Records of controlled substances lost, destroyed or stolen, shall contain a detailed list of the kind and quantity of such drugs and the date of discovery of such loss, destruction or theft. Iowa Code section 124.306.

The Board's rules governing controlled substance record keeping are found at 657 IAC 10.34. The rules are consistent with Iowa Code section 124.306 but further provide that records must be kept by the registrant and available for inspection or copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in these rules.¹³ Controlled substance records shall be maintained in *readily retrievable manner* that establish the receipt and distribution of controlled substances. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a *secure storage area* outside the licensed pharmacy department, but the remote storage area shall be located within the same physical structure containing the licensed pharmacy department. 657 IAC 10.34 (emphasis added). 657 IAC 8.9 includes these same requirements.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated Iowa Code section 124.306 and 657 IAC 10.34 by failing to create and maintain required documentation of the pharmacy's invoices for the purchase of hydrocodone and for failure to maintain annual inventories of its hydrocodone products. Respondents failed to ensure that invoices were

¹³ As discussed at hearing, Schedule II-V controlled substance prescriptions are valid for six months and may be authorized for up to five refills. See 657 IAC 10.28. Records of controlled substance prescriptions must be kept for two years from the last refill date.

properly signed and dated and failed to maintain controlled substances invoices and inventories in a readily retrievable manner. In addition, many records, including confidential prescription records, were stored in the pharmacy's basement, which was not secure.

***Count IV: Bauder Pharmacy and Mark Graziano
Failure to Properly Sign and Date Invoices for Controlled Substances***

657 IAC 8.9(1) requires all pharmacies to maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded. The invoices must be maintained for at least two years.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.9(1) by not maintaining all supplier invoices for a period of two years and by not ensuring that a pharmacist or other responsible individual signed the invoice to clearly record receipt of the controlled substances listed on the invoice.

***Count V: Bauder Pharmacy and Mark Graziano
Dispensing Schedule II Controlled Substances in Quantities Exceeding Prescriber
Authorization***

657 IAC 10.21(5) authorizes a pharmacist, after consultation with the prescriber or the prescriber's agent and documentation of such consultation, to change the drug strength, dosage form, or drug quantity on a Schedule II controlled substance prescription. During the March 16, 2012 pharmacy inspection, Jean Rhodes found a prescription for oxycontin 20mg/ml that was written for 10 ml. The manufacturer supplied the drug as a 30ml container and this is what the pharmacy dispensed, but there was no documentation that the prescriber authorized the change. Following the inspection, Mark Graziano corrected this deficiency by obtaining a corrected prescription from the prescriber. The Board concluded that this corrected deficiency involving one prescription does not merit finding a separate violation against Respondents.

***Count VI: Bauder Pharmacy and Mark Graziano
Failure to Comply with Requirements for Partial Filling***

657 IAC 10.23 is the Board's rule regulating partial filling of Schedule II controlled substances. If a pharmacy is unable to supply the full quantity called for in a prescription, the pharmacists may partially fill a prescription, so long as the pharmacist notes the quantity provided on the prescription record and the remaining portion of the prescription is filled within 72 hours of the first partial filling. No further quantity may be supplied beyond 72 hours without a new prescription.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.23 when they partially filled Schedule II prescriptions and then filled the balance of the prescription more than 72 hours after the partial filling. This deficiency was specifically cited at the time of the March 16, 2012 inspection.

***Count VII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete and Accurate Perpetual Inventories of Schedule II
Controlled Substances***

657 IAC 10.33 requires all pharmacies that dispense Schedule II controlled substances to maintain a perpetual inventory system for all Schedule II controlled substances in accordance with the rule. The perpetual inventory must be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

The perpetual inventory may be maintained in a manual or electronic format. 657 IAC 10.33(1). The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by nation drug code (NDC) number. The record shall be updated to identify each prescription filled and each shipment received. 657 IAC 10.33(2). The pharmacist in charge shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the pharmacist in charge shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 10.16(124) and to the DEA pursuant to DEA regulations. 657 IAC 10.33(4).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.33 when they failed to maintain a complete and accurate perpetual inventory of Schedule II controlled substances. At the time of the March 16, 2012 inspection, the perpetual inventory for Schedule II controlled substances had multiple negative balances due to errors in the way the pharmacy was partially filling Schedule II controlled substances. When a Schedule II prescription was partially filled, the actual amount dispensed should have been recorded. When the pharmacy dispensed the owed quantity on the prescription, there should have been a separate entry.

***Count VIII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete and Accurate Inventory of Controlled Substances***

All registrants are required to take an initial inventory of all stocks of controlled substances on hand on the date the registrant commences business and is thereafter required to take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within one year of the previous inventory date. 657 IAC 10.35(2),(3). Each inventory record must comply with the requirements of subrule 10.35 and must be maintained for a minimum of two years from the date of the inventory. 657 IAC 10.35(1). Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken. 657 IAC 10.35(1)(a).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 10.35 when they failed to maintain complete and accurate inventories of the Schedule III controlled substances. Respondents clearly were not maintaining accurate inventories when many hundreds of thousands of hydrocodone were missing from the pharmacy.

***Count IX: Bauder Pharmacy and Mark Graziano
Failure to Document Verification of Controlled Substance Refills***

657 IAC 21.5 requires the individual pharmacist who makes use of the pharmacy prescription application to provide documentation of the fact that the refill information entered into the pharmacy prescription application each time the pharmacist refills an original written, fax, or oral prescription order for a controlled substance is correct.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 21.5 when they failed to document verification of controlled substance refills for a period of two years. This deficiency was noted during the March 16, 2012 inspection and was cited in the March 22, 2012 inspection report. Mark Graziano admitted to Jean Rhodes that he did not understand this requirement. He believed that his reports to the PMP provided sufficient documentation of verification.

***Count X: Bauder Pharmacy and Mark Graziano
Failure to Properly Supervise Dispensing Functions Delegated to Non-
Pharmacists***

This count cites 657 IAC 3.20, which states that the ultimate responsibility for the actions of a pharmacy technician shall remain with the supervising pharmacist. The Board was unable to find any evidence to support a separate violation under this count. The pharmacy and pharmacist in charge were responsible for the pharmacy technician's failure to have a current registration for more than two years, but this violation is addressed in Count XII.

***Count XI: Bauder Pharmacy and Mark Graziano
Failure to Maintain Complete Patient Records***

657 IAC 6.13(1) specifies the patient record system that must be maintained by all pharmacies. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for obtaining, recording, and maintaining the following information: *a.* known allergies;...*g.* [p]harmacist comments relevant to the individual's drug therapy, including (1) known drug reactions, ... (3) [k]nown chronic disease conditions or disease states of patients, (4) [t]he identity of other drugs, over-the-counter drugs, herbals, other alternative medications, ...that may relate to prospective drug review.

This count relates to the two shopper survey reports. One shopper reported that she was not asked for any patient history, current health conditions, medications or allergies when her new prescription was filled by Mark Graziano. The second shopper reported that she was asked about allergies but was not asked about disease states or other medications that she was taking. The shoppers did not

testify at hearing and the record does not include the pharmacy's patient records for the two shoppers. The Board declined to find separate violations with respect to this count.

***Count XII: Bauder Pharmacy and Mark Graziano
Failure to Ensure All Pharmacy Technicians Have Current Registration***

657 IAC 3.11(2) provides that a pharmacy technician registration that is not renewed before its expiration date shall be delinquent, and the registrant shall not continue employment as a pharmacy technician until the registration is reactivated. An individual who continues employment as a pharmacy technician without a current registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue to practice as a pharmacy technician, may be subject to disciplinary sanctions. See also 657 IAC 36.1(4)(aa).

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 3.11(2) and 36.1(4)(aa) when they permitted Jennifer Higgins to continue working as a pharmacy technician for nearly eighteen months after her pharmacy technician registration had expired.

***Count XIII: Bauder Pharmacy and Mark Graziano
Failure to Maintain Policies and Procedures for the Operation of the Pharmacy***

657 IAC 6.2(14) provides that there must be one professionally competent, legally qualified pharmacist in charge of each pharmacy who is responsible for establishing and implementing policies and procedures for all operations of the pharmacy. The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 6.2(14) by failing to have adequate written policies and procedures for all operations of the pharmacy. It is the responsibility of the pharmacist in charge to establish and implement policies and procedures for all operations of the pharmacy. The March 22, 2012 inspection report and the credible testimony of Jean Rhodes establishes that there were only minimal policies and procedures for Bauder Pharmacy, mostly relating to interns, at the time of the March 16th inspection. The pharmacy did not even have interns at the time of the inspection. In addition, when Ms. Rhodes returned to Bauder Pharmacy on October 11, 2012, pharmacist in charge Kim Robertson was unable to provide the policies and procedures for the operation of the pharmacy. While Respondents assert that the black binder the Board acquired between May and October, 2012 contained documents that

satisfied this requirement, the Board's examination of the materials contained in the binder does not support this assertion.

***Count XIV: Bauder Pharmacy and Mark Graziano
Failure to Provide Proper Security for Prescription Medications and Pharmacy
Records Stored in Basement***

657 IAC 6.7 provides that while on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for the effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657-Chapter 21. The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site, except as provided in subrule 6.7(2). The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 6.7 when they stored prescription medications and confidential patient records in the pharmacy's basement, which was unlocked and not protected from unauthorized access.

***Count XV: Mark Graziano
Failure to Wear an Identification Badge***

657 IAC 8.4(4) requires pharmacists to wear a visible identification badge while on duty that clearly identifies the person as a pharmacist and includes at least the pharmacist's first name. The preponderance of the evidence established that Mark Graziano violated 657 IAC 8.4(4) when he repeatedly failed to wear an identification badge while working in the pharmacy.

***Count XV: Bauder Pharmacy and Count XVI: Mark Graziano
Failure to Have Required Policies, Procedures and Documentation for Pharmacy
Technician Training***

657 IAC 8.14 requires all Iowa-licensed pharmacies utilizing pharmacy technicians or pharmacy support persons to develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Pharmacy technician and support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy

technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.14 when they failed to establish policies and procedures for the training and utilization of pharmacy technicians and failed to document pharmacy technician and support person training. This deficiency was documented in the March 22, 2012 inspection report and the credible testimony of Jean Rhodes. In addition, when Jean Rhodes returned to the pharmacy on October 11, 2012 to review the deficiency corrections with then pharmacist in charge Kim Robertson, the pharmacy still did not have a technician training policy. While Respondents assert that the black binder the Board acquired between May and October, 2012 contained documents that satisfied this requirement, the Board's examination of the materials contained in the binder does not support this assertion.

***Count XVI: Bauder Pharmacy and Count XVII: Mark Graziano
Failure to Have a Continuous Quality Improvement Program***

657 IAC 8.26 requires all licensed pharmacies to implement and participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and quality of patient care.

The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of the rule.¹⁴ Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel.¹⁵

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.26 by failing to have a written CQI program. This deficiency was documented in the March 22, 2012 inspection report and the credible testimony of Jean Rhodes. In addition, when Jean Rhodes returned to

¹⁴ 657 IAC 8.26(2).

¹⁵ 657 IAC 8.26(3).

the pharmacy on October 11, 2012 to review the deficiency corrections with then pharmacist in charge Kim Robertson, the pharmacy still did not have a technician training policy. While Respondents assert that the black binder the Board acquired between May and October, 2012 contained documents that satisfied this requirement, the Board's examination of the materials contained in the binder does not support this assertion.

***Count XVII: Bauder Pharmacy and Count XVIII: Mark Graziano
Failure to Meet Minimum Standards for Sterile Compounding***

"Sterile compounding" means the aseptic processing in a clean environment of any pharmaceutical preparations that are required to be sterile when they are administered into patient body cavities, central nervous and vascular systems, eyes and joints,..., including but not limited to injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions)...¹⁶ 657 IAC Chapter 13 is entitled "Sterile Compounding Practices" and establishes the standards and procedures for the preparation, labeling, and distribution of sterile preparations by licensed pharmacies pursuant to a practitioner's order or prescription.¹⁷

657 IAC 13.3(1) provides that each pharmacy shall have a pharmacist responsible for ensuring that:

- a. Preparations are accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.
- b. Appropriate cleanliness conditions are maintained, including preservation of the sterile environment during the compounding process.
- c. Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen beyond-use date or, if a written standard is not available, a maximum 24-hour expiration shall be used.
- d. Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits.

¹⁶ 657 IAC 13.2.

¹⁷ 657 IAC 13.1.

Each pharmacy that performs sterile compounding is also required to have a written quality assurance procedure.¹⁸

657 IAC 13.3(3) provides that all personnel involved with compounding, repackaging, or manipulating sterile preparations shall be adequately educated and trained. Training shall include written documentation certifying that the compounding personnel are able to adequately complete the activities listed in subsections "a" to "f."

657 IAC 13.6 requires pharmacies performing sterile compounding to have a written policy and procedure manual for the compounding, dispensing, delivery, administration, storage, and use of sterile preparations. The manual shall establish policies and procedures relating to subjects identified in this rule and other rules within 657 IAC chapter 13.

657 IAC 13.31 requires pharmacies to establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care.

Mark Graziano was the only pharmacist performing sterile compounding at Bauder Pharmacy. Mr. Graziano was responsible for developing all required policies and procedures for sterile compounding, including the development of a written quality assurance procedure. Mr. Graziano was also responsible for documenting that he was adequately educated and trained. The preponderance of the evidence established that Respondents Bauder Pharmacy and Mark Graziano violated 657 IAC 13.3, 13.3(2), 13.6, and 13.31 by failing to develop and implement written policies and procedures for sterile compounding, including failure to adopt a written quality assurance program. Bauder Pharmacy and Mark Graziano violated 657 IAC 13.3(3) by failing to document appropriate education, training, and proficiency of the pharmacy's compounding personnel.

657 IAC 13.7(2) relates to batch preparation and requires each container of a batch preparation compounded in anticipation of later dispensing to bear a label with at least the following information: name and quantity of all contents, internal code to identify the date and time of preparation and the preparer's and reviewing pharmacist's initials or unique identifiers, stability (beyond-use date)

¹⁸ 657 IAC 13.3(2).

as set forth in the pharmacy's policy and procedure manual, and auxiliary labels as needed.

The preponderance of the evidence established that at the time of the March 16, 2012 pharmacy inspection, the refrigerator in the sterile compounding area of Bauder Pharmacy had two unlabeled vials of HCG injectable, and there were no batch records for the product, in violation of 657 IAC 13.7(2).

657 IAC 13.11 establishes maximum storage periods for low-risk preparations. In the absence of the preparation passing a sterility test and provided the preparation is properly stored before administration, the storage periods shall not exceed 14 days at a cold temperature. 657 IAC 13.11(1)"d"(2).

The preponderance of the evidence established that Mark Graziano had assigned a 30 day beyond-use date to Lupron injections that were only permitted to have a 14 day beyond-use date.

657 IAC 13.25 requires the pharmacy to develop, maintain, and implement written procedures that include appropriate media-fill testing (MFT) by personnel authorized to compound preparations. Each person authorized to compound low-risk preparation shall annually perform a successful MFT procedure. 657 IAC 13.25(1).

The preponderance of the evidence established that Mark Graziano had never performed media-fill testing, in violation of 657 IAC 13.25. Mr. Graziano ordered a kit that was to be delivered in May 2012, but the pharmacy ceased performing sterile compounding after Mr. Graziano's pharmacist license was suspended, effective May 10, 2012.

657 IAC 13.27 requires, in part, that the primary engineering control device was to be placed in a buffer area with cleanable, nonshedding, smooth surfaces; all junctures shall be covered; and all cracks and crevices shall be caulked. 657 IAC 13.28 requires the pharmacy to have appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations.

The preponderance of the evidence established that several junctures in the buffer area needed recaulking and that peeling paint needed to be repaired, in violation of 657 IAC 13.27. The preponderance of the evidence further

established that the pharmacy did not have written cleaning procedures or any documentation of cleaning, in violation of 657 IAC 13.28. Jean Rhodes was able to verify that these particular deficiencies had been corrected as of April 12, 2012.

657 IAC 13.29(1) requires all cleanrooms, laminar airflow workbenches, and barrier isolators to be certified by an independent contractor according to ISO Standards at least every six months. 657 IAC 13.29(2) requires the pharmacy to establish written procedures, appropriate to the risk level preparations compounded by the pharmacy, which must include environmental testing, end testing, and evaluation of validation results. 657 IAC 13.29(2)(a) and (b) requires pharmacies to perform microbial air sampling and pressure differential monitoring.

The preponderance of the evidence established that Bauder Pharmacy only obtained certification of its clean rooms yearly, rather than every six months, in violation of the requirements of 657 IAC 13.29(1). The March 22, 2012 Inspection Report was the second notice on this violation. In addition, Bauder Pharmacy had never performed microbial sampling, had no pressure differential monitors, and had no procedures concerning environmental requirements. These deficiencies were not corrected by the pharmacy within 30 days.

***Count XVIII: Bauder Pharmacy and Count XIX: Mark Graziano
Failure to Provide Labeling and Record Keeping for Med Paks***

In lieu of dispensing prescribed drug products in conventional prescription containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized medication package (patient med pak) pursuant to the requirements of 657 IAC 22.5. A patient med pak is a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.¹⁹

The patient med pak shall be labeled as provided by 657 IAC 22.5(5), with the patient's name; a unique identification number for the patient and med pak and a separate identification number for each of the prescription drug orders for each of the drug products contained in the med-pak; the name, strength, dosage form, and total quantity of the drug; directions for use of each drug product;

¹⁹ 657 IAC 22.5(1).

name of prescriber for each drug product; the date of preparation of the patient med-pak and the assigned beyond-use date; the name, address, and telephone number of the pharmacy; and the initials or unique identification of the responsible pharmacist.²⁰ Pharmacies are also required to keep records of all med-paks.²¹

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 22.5 by failing to provide labeling and recordkeeping for the medpaks that it prepared for four customers.

***Count XIX: Bauder Pharmacy and Count XX: Mark Graziano
Failure to Provide Adequate Patient Counseling***

Patient counseling is required by Board rule.²² Pharmacists and pharmacies may be disciplined for attempting to circumvent patient counseling requirements or discouraging patients from receiving patient counseling concerning their prescription drug orders.²³ These counts were based on the shopper survey reports. Although the patient counseling reported by the two shoppers appeared to fall below Board expectations, the Board concluded that there was insufficient evidence to support separate findings of violation on these counts.

***Count XX: Bauder Pharmacy
Failing to Report Change in Pharmacist in Charge and Failing to Comply With
Requirements for Making the Change***

Iowa Code section 155A.19(1)(d) requires pharmacies to report to the Board, in writing, any change in the pharmacist in charge. 657 IAC 8.35(6)(c) requires a pharmacy to notify the Board, in writing, of a temporary pharmacist in charge within 10 days following a vacancy in the pharmacist in charge position. A permanent pharmacist in charge shall be identified within 90 days following the vacancy.

Effective May 10, 2012, the Board suspended the pharmacist license of Mark Graziano, who was the pharmacist in charge of Bauder Pharmacy. During a visit to the pharmacy on June 20, 2012, Compliance Officer Jean Rhodes had

²⁰ 657 IAC 22.5(5).

²¹ *Id.*

²² See 657 IAC 6.14.

²³ 657 IAC 36.1(4)(w).

reminded Kim Robertson, R.Ph. that the pharmacy still had not identified a pharmacist in charge. The preponderance of the evidence established that Bauder Pharmacy violated Iowa Code section 155A.19(1)(d) and 657 8.35(6)(c) when it waited until July 23, 2012 to notify the Board that Kim Robertson was the new pharmacist in charge.

Count XXI: Mark Graziano

Failing to Meet the Requirements for Practicing as Pharmacist in Charge

657 IAC 6.2 provides, in relevant part:

657-6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

...

6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

7. Delivering drugs to the patient or the patient's agent.

...

9. Training pharmacy technicians and pharmacy support persons.

10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

11. Distributing and disposing of drugs from the pharmacy.

12. Maintaining records of transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.

13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.

14. Establishing and implementing policies and procedures for all operations of the pharmacy.

15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the

storage of prescription drugs, devices and controlled substances and to support the operations of the pharmacy.

The preponderance of the evidence established that Mark Graziano's performance as pharmacist in charge of Bauder Pharmacy was completely inadequate and failed to properly fulfill the above-listed responsibilities of the pharmacist in charge, in violation of 657 IAC 6.2.

***Count XXI: Bauder Pharmacy and Count XXII: Mark Graziano
Failing to Comply with Board Rules Regarding Manner of Issuance of
Prescription Drug or Medication Order***

657 IAC 8.19 specifies the manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in 657-21.9, or by electronic transmission in accordance with applicable federal and state laws, rules and regulations. Any prescription drug order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in 657-21.7.

A written, electronic, or facsimile prescription shall include: the date issued, the name and address of the patient, the name, strength, and quantity of the drug or device prescribed, the name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number, and the written or electronic signature of the prescriber.²⁴

A prescription transmitted via facsimile shall include the identification number of the facsimile machine used to transmit the prescription to the pharmacy, the time and date of transmission, the name, address, telephone number and facsimile number of the pharmacy to which the prescription is being transmitted, and the manual signature of the prescriber if the prescription is for a controlled substance.²⁵

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano repeatedly violated 657 IAC 8.19. A review of 614 randomly selected

²⁴ 657 IAC 8.19(1)(a).

²⁵ 657 IAC 8.19(1)(c).

prescriptions that were filled by the pharmacy between 2008 and 2012 revealed that only 166 of the prescriptions were legally correct. The remaining 448 prescriptions were incorrect or incomplete in one of the following respects:

- Sender's information cut off from fax;
- Wrong patient;
- Wrong prescriber;
- Wrong medication;
- No prescriber signature or verification;
- Wrong number of refills;
- Wrong directions;
- No prescriber DEA number for controlled substances;
- Faxed prescription not signed by prescriber;
- Wrong dispensed quantity;
- Filled beyond authorized time period;
- Filled prior to authorization;
- RX denied by prescriber but filled by pharmacy;
- No prescribed quantity;
- RX number not recorded on prescription;
- Dispensed generic when prescription indicated "Do not substitute."

***Count XXII: Bauder Pharmacy and Count XXIII: Mark Graziano
Failing to Comply with Board Rule Regarding Controlled Substance
Prescription Requirements***

657 IAC 10.21 provides that all prescriptions for controlled substances shall be dated as of, and signed on the date issued. Controlled substances prescriptions shall be valid for six months following the date of issue. A prescription for Schedule II, IV or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled.

657 IAC 10.21(1) *Form of prescription.* All prescriptions shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed and directions for use; and the name, address, and DEA registration number of the prescriber...A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

Androgel is an anabolic steroid that has also been placed in Schedule III.²⁶ The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano repeatedly violated 657 IAC 10.21 when Androgel was dispensed by the pharmacy without obtaining a legally correct prescription from a prescriber. The Androgel prescriptions reviewed by the Board's compliance officers including the following deficiencies:

- No Dr. DEA number;
- No hardcopy in file;
- No prescriber signature;
- Stamped prescriber signature;
- Unauthorized refills dispensed;
- Refilled beyond 6 months;
- Initial file after prescription had expired (6 months);
- No patient name on hard copy prescription;
- No notation of verbal authorization;
- No RX number on prescription;
- Sender information cut off from fax;
- Wrong dosage form of medication;
- Filled prior to receipt of fax authorization.

***Count XXIII: Bauder Pharmacy and Count XXIV
Failing to Comply with Board Rules Regarding Faxed Prescriptions***

657 IAC 21.9 permits a pharmacist to dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. The faxed prescription drug order shall serve as the original prescription, shall be maintained for a minimum of two years from the date of last fill or refill, and shall contain all information required by Iowa Code section 155A.27, including the prescriber's signature or electronic signature. The faxed prescription drug order, if transmitted by the practitioner's agent, shall identify the transmitting agent by first and last names and title and shall include the prescriber's signature or electronic signature. A prescription for a controlled substance shall include the prescriber's manual signature. 657 IAC 21.3 addresses the pharmacist's responsibility to verify the authenticity of an electronically prepared or electronically or fax transmitted prescription.

²⁶ Iowa Code section 124.208(6)(be).

The Board believes that Respondents' violations with respect to deficiencies in its faxed prescriptions have been adequately addressed under the prior two counts (Counts XXII and XXIII for Bauder Pharmacy and Counts XXIII and XXIV for Mark Graziano) The Board believes it is unnecessary to find additional violations under these counts.

***Count XXIV: Bauder Pharmacy and Count XXV: Mark Graziano
Failing to Comply with Board Rules Regarding Prescription Processing
Documentation***

657 IAC 6.8 requires all prescriptions to be dated and assigned a unique identification number that shall be recorded on the original prescription. The original prescription, whether transmitted orally, electronically, or in writing, shall be retained by the pharmacy. Refill documentation shall include date of refill and the initials or other unique identification of the pharmacist. Upon review of the record, the Board believes that the pharmacy had the required logs, although they were not signed by a pharmacist. The Board declines to find additional violations under these counts.

***Count XXV: Bauder Pharmacy and Count XXVI: Mark Graziano
Failing to Comply with Board Rules Regarding Record Retention Requirements***

657 IAC 8.9 provides that each inventory or other record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular record or inventory. Original hard copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department. The following records shall be maintained for at least two years.

8.9(1) Drug supplier invoices. All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded.

...

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated 657 IAC 8.9 by failing to retain all drug supplier invoices for a minimum period of two years and by failing to record the date of receipt of controlled substances on all of the invoices.

***Count XXVI: Bauder Pharmacy and Count XXVII: Mark Graziano
Dispensing Controlled Substances Without a Prescription***

Iowa Code section 124.308(4) provides that except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance in Schedule III or IV, which is a prescription drug as determined under chapter 155A, shall not be dispensed without a written or oral prescription of a practitioner or without an electronic or facsimile prescription in accordance with subsection 5.

The preponderance of the evidence established that Bauder Pharmacy and Mark Graziano violated Iowa Code section 124.308(4) by the repeated dispensing of large numbers hydrocodone tablets without a proper prescription. The factual basis for this violation was fully discussed in connection with Count I. In addition, Respondents violated Iowa Code section 124.308(4) when Androgel was repeatedly dispensed without a valid prescription. The Board declined to find a violation under this count with respect to the prescriptions filled at Bauder Pharmacy for CG.

Sanctions

The Board may consider the following factors in determining the nature and severity of disciplinary sanctions: the relative seriousness of the violation as it relates to assuring citizens of this state a high standard of professional care, the facts of the particular violation, any extenuating circumstances or other countervailing considerations, the number of prior violations or complaints, seriousness of prior violations or complaints, whether remedial action has been taken, and any other factors as may reflect upon the competency, ethical standards, and professional conduct of the licensee, registrant, or permittee.²⁷

The record includes a table summarizing prior cases where the Board has disciplined pharmacies and/or pharmacists for illegal diversion of or failure to properly account for controlled substances. (State Exhibit 77). The table

²⁷ 657 IAC 36.1(3).

provides minimal information about the particular facts of those cases. It is, however, abundantly clear to the Board that the violations in this case are far more egregious than these prior cases. This case involves far larger numbers of missing hydrocodone tablets as well as compelling evidence that the pharmacist in charge, who is also the majority owner of the pharmacy, was directly involved in the illegal distribution of the drugs. The violations established in this Decision and Order seriously threatened the public health, safety, and welfare.

In addition, a number of Respondents' other violations, including but not limited to the violations involving sterile compounding, also raise grave concerns for public health and safety. The Board's findings of violation in this case more than justify imposing the most severe disciplinary sanctions available to the Board, including permanent revocation of Mark Graziano's license to practice pharmacy and revocation of Bauder Pharmacy's controlled substance registration.

With respect to the pharmacy's controlled substance registration, it is true, as pointed out by the state, that the Order of Immediate Suspension and Order to Show Cause stated: **IF YOU DESIRE A HEARING REGARDING SUSPENSION AND POSSIBLE 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...IF RESPONDENT DOES NOT REQUEST HEARING IN THIS MATTER WITHIN THIRTY DAYS OF THE DATE OF THIS ORDER, RESPONDENT'S CONTROLLED SUBSTANCE REGISTRATION WILL BE DEEMED REVOKED WITHOUT FURTHER ORDER OF THE BOARD.** (Emphasis original)

In its brief filed on the day of the hearing, the state asserted that Bauder Pharmacy's controlled substances registration has already been "deemed revoked" because Bauder Pharmacy did not file a request for hearing on the immediate suspension of its controlled substances registration. Respondent's counsel did not specifically respond to this argument at hearing.

A review of the Board's legal file does not reveal any specific written request from Bauder Pharmacy for a hearing on the issue of the immediate suspension of its controlled substances registration. Nevertheless, the Board notes that the initial Order Granting Motion for Continuance, which was issued by the Board on May 15, 2012, states:

On May 11, 2012, the Respondents, Bauder Pharmacy, Inc. and Mark E. Graziano, through attorneys Mark Weinhardt and George LaMarca, requested a continuance of the hearing on the statement of charges, emergency order, and order of immediate suspension and order to show cause against the Respondents, Bauder Pharmacy, Inc. and Mark E. Graziano. Respondents have provided sufficient justification for its motion for continuance.

This continuance order could be interpreted as the Board's acknowledgement that Bauder Pharmacy, Inc. did request a hearing on the Order for Immediate Suspension and Order to Show Cause. For this reason, the Board has elected to consider and address the issue of Respondent's controlled substance registration in this Decision and Order, rather than "deeming" the controlled substance registration to have been revoked.

DECISION AND ORDER

IT IS THEREFORE ORDERED that pharmacist license number 16752, issued to Mark Graziano, is hereby PERMANENTLY REVOKED.

IT IS FURTHER ORDERED that controlled substance registration number 1100280, issued to Bauder Pharmacy, Inc., is hereby REVOKED.

IT IS FURTHER ORDERED that pharmacy license number 222, issued to Bauder Pharmacy, Inc., is hereby issued a CITATION and WARNING for the violations of Board statutes and rules established in this Decision and Order.

IT IS FURTHER ORDERED that pharmacy license number 222, issued to Bauder Pharmacy, Inc., is hereby placed on INDEFINITE PROBATION, subject to the following terms and conditions:

- A. Respondent Bauder Pharmacy, Inc. shall pay a civil penalty in the amount of \$25,000. 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 thirty (30) days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

B. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, a written plan of action for correcting all remaining deficiencies identified in this Decision and Order.

C. Respondent Bauder Pharmacy, Inc. is hereby prohibited from performing any sterile compounding, unless otherwise ordered by the Board. The pharmacy shall not request permission to resume sterile compounding until such time as the pharmacist in charge can verify proper training of staff and the adoption of policies and procedures for sterile compounding in accordance with Board rules and approved by the Board.

D. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, policies and procedures for all operations of the pharmacy.

E. Within thirty (30) days of the issuance of this Decision and Order, Respondent Bauder Pharmacy, Inc. shall submit, for Board approval, a Quality Control Improvement (CQI) plan.

F. Respondent Bauder Pharmacy, Inc. shall obtain Board approval for every pharmacist in charge of the pharmacy.

G. Mark Graziano shall be allowed no access to the pharmacy department or to prescription drugs within the pharmacy.

H. There shall be quarterly inspections of Bauder Pharmacy, Inc. to ensure full compliance with the rules governing pharmacy practice. Such inspections shall be conducted by a consultant approved by the Board, and shall be at the pharmacy's expense. The pharmacy shall comply with all recommendations made by the consultant. The pharmacy and the consultant shall submit quarterly reports to the Board. The reports shall be filed not later than March 5, June 5, September 5, and December 5 of each year of the indefinite probation.

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondents Mark Graziano and Bauder Pharmacy shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the

executive secretary/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 thirty (30) days of receipt of the bill.

Dated this 5th day of November, 2013



Edward Maier

Chairperson

Iowa Board of Pharmacy

cc: Meghan Gavin and Laura Cathelyn, Assistant Attorneys General
Rick Olson, Respondents' Attorney

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

Pharmacy License of)	Case No. 2012-52
BAUDER PHARMACY, INC.)	
License No. 222,)	NOTICE OF HEARING &
Respondent.)	STATEMENT OF CHARGES
)	

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) (2013). Respondent was issued Iowa license 222. Respondent's license is currently active.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on November 17, 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 over this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C.

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, 155A, and 272C 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 BEHAVIOR OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC

Respondent is charged with engaging in unethical behavior or practice harmful or detrimental to the public in violation of Iowa Code sections 147.55(3) and 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(c); (u).

Count II

HAVING AN OWNER WHO HAS VIOLATED IOWA CODE CHAPTER 155A AND BOARD RULES

Respondent is charged with having an owner who has violated Iowa Code chapter 155A and board rules in violation of Iowa Code sections 147.55(8) and 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(u)

Count III

VIOLATION OF A BOARD ORDER IN A DISCIPLINARY CASE

Respondent is charged with violation of a board order in a disciplinary case in violation of Iowa Code sections 155A.15(2)(c) and 272C.3(2)(a) and 657 Iowa Administrative Code rule 36.1(4)(i); (u).

Count IV

FAILURE TO MAINTAIN SECURITY

Respondent is charged with failing to maintain the security of the prescription

department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs in violation of Iowa Code sections 155A.15(2)(c) and 657 Iowa Administrative Code rules 6.7, 8.3(1), 8.5(3), and 36.1(4)(u).

D. FACTUAL CIRCUMSTANCES

1. On April 5, 2013, the Board issued its Findings of Fact, Conclusions of Law, Decision and Order in a disciplinary case concerning the Respondent and majority-owner Mark Graziano.¹

2. The Board's April 5th order found approximately twenty violations against owner Mark Graziano, including numerous violations of Iowa Code chapter 155A and board rules.

3. On the Respondent's December 5, 2013 pharmacy license renewal, Mark Graziano was once again listed as an owner of the Respondent pharmacy.

4. The Board's April 5th order also placed Respondent's pharmacy license on "indefinite probation," subject to a number of terms and conditions. Amongst other things, the Order required the Respondent to prohibit Mark Graziano from having access to the pharmacy department or to prescription drugs within the pharmacy, "comply with all recommendations made by the [Board-approved] consultant," and submit quarterly reports by the Respondent and the consultant detailing the Respondent's full compliance with all recommendations made by the consultant. The quarterly reports were to be submitted on the 5th day of March, June, September, and December of each year. The consultant, moreover, is required to conduct quarterly inspections of the pharmacy.

5. To date, Mark Graziano continues to have access to the Respondent's pharmacy department, including having keys and the alarm code for the pharmacy. No secure, physical barrier exists between the pharmacy department and the drug store/soda fountain.

6. The Respondent, through owner Mark Graziano, terminated its first consultant and was without a consultant for several months. The initial consultant's work was stymied by the continued and, at times, harassing interference of Mark Graziano.

7. To date, the Respondent's current consultant Tom Crabb has yet to submit a quarterly report. Without quarterly reports, it is impossible for the Board to determine whether the required quarterly inspections were conducted.

8. To date, the Respondent has only submitted two of the six required quarterly reports.

9. Numerous other aspects of the Board Order, including submission of corrective action plan, submission of a Continuous Quality Improvement plan, and payment of the \$25,000 civil

¹ Following a limited remand, the Board's initial order was upheld in its entirety with minor factual amendments.

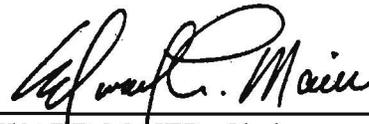
penalty and hearing fees were completed. Each of these requirements, however, was completed in an untimely fashion inconsistent with the Board's Order.

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 16th day of October, 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

Rick L. Olson
2635 Hubbell Ave.
Des Moines, IA 50317
ATTORNEY FOR RESPONDENT

Proof of Service	
The undersigned certifies that the foregoing instrument was served in the following manner on the 17th day of October, 2014.	
<input type="checkbox"/> U.S. Mail	<input type="checkbox"/> Fax
<input type="checkbox"/> Hand Delivery	<input type="checkbox"/> Overnight Courier
<input type="checkbox"/> Federal Express	<input type="checkbox"/> Other
<input checked="" type="checkbox"/> Electronically	
Signature: <u>Becky Hall</u>	

BEFORE THE IOWA BOARD OF PHARMACY

Pharmacy License of)	Case No. 2012-52
BAUDER PHARMACY, INC.)	
License No. 222,)	CORRECTED
Respondent.)	NOTICE OF HEARING &
)	STATEMENT OF CHARGES

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) (2013). Respondent was issued Iowa license 222. Respondent’s license is currently active.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on November 18, 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 over this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C.

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, 155A, and 272C 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 BEHAVIOR OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC

Respondent is charged with engaging in unethical behavior or practice harmful or detrimental to the public in violation of Iowa Code sections 147.55(3) and 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(c); (u).

Count II

HAVING AN OWNER WHO HAS VIOLATED IOWA CODE CHAPTER 155A AND BOARD RULES

Respondent is charged with having an owner who has violated Iowa Code chapter 155A and board rules in violation of Iowa Code sections 147.55(8) and 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(u)

Count III

VIOLATION OF A BOARD ORDER IN A DISCIPLINARY CASE

Respondent is charged with violation of a board order in a disciplinary case in violation of Iowa Code sections 155A.15(2)(c) and 272C.3(2)(a) and 657 Iowa Administrative Code rule 36.1(4)(i); (u).

Count IV

FAILURE TO MAINTAIN SECURITY

Respondent is charged with failing to maintain the security of the prescription

department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs in violation of Iowa Code sections 155A.15(2)(c) and 657 Iowa Administrative Code rules 6.7, 8.3(1), 8.5(3), and 36.1(4)(u).

D. FACTUAL CIRCUMSTANCES

1. On April 5, 2013, the Board issued its Findings of Fact, Conclusions of Law, Decision and Order in a disciplinary case concerning the Respondent and majority-owner Mark Graziano.¹

2. The Board's April 5th order found approximately twenty violations against owner Mark Graziano, including numerous violations of Iowa Code chapter 155A and board rules.

3. On the Respondent's December 5, 2013 pharmacy license renewal, Mark Graziano was once again listed as an owner of the Respondent pharmacy.

4. The Board's April 5th order also placed Respondent's pharmacy license on "indefinite probation," subject to a number of terms and conditions. Amongst other things, the Order required the Respondent to prohibit Mark Graziano from having access to the pharmacy department or to prescription drugs within the pharmacy, "comply with all recommendations made by the [Board-approved] consultant," and submit quarterly reports by the Respondent and the consultant detailing the Respondent's full compliance with all recommendations made by the consultant. The quarterly reports were to be submitted on the 5th day of March, June, September, and December of each year. The consultant, moreover, is required to conduct quarterly inspections of the pharmacy.

5. To date, Mark Graziano continues to have access to the Respondent's pharmacy department, including having keys and the alarm code for the pharmacy. No secure, physical barrier exists between the pharmacy department and the drug store/soda fountain.

6. The Respondent, through owner Mark Graziano, terminated its first consultant and was without a consultant for several months. The initial consultant's work was stymied by the continued and, at times, harassing interference of Mark Graziano.

7. To date, the Respondent's current consultant Tom Crabb has yet to submit a quarterly report. Without quarterly reports, it is impossible for the Board to determine whether the required quarterly inspections were conducted.

8. To date, the Respondent has only submitted two of the six required quarterly reports.

9. Numerous other aspects of the Board Order, including submission of corrective action plan, submission of a Continuous Quality Improvement plan, and payment of the \$25,000 civil

¹ Following a limited remand, the Board's initial order was upheld in its entirety with minor factual amendments.

penalty and hearing fees were completed. Each of these requirements, however, was completed in an untimely fashion inconsistent with the Board's Order.

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 20th day of October, 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

Rick L. Olson
2635 Hubbell Ave.
Des Moines, IA 50317
ATTORNEY FOR RESPONDENT

Proof of Service	
The undersigned certifies that the foregoing instrument was served in the following manner on the 20th day of October, 2014.	
<input type="checkbox"/> U.S. Mail	<input type="checkbox"/> Fax
<input type="checkbox"/> Hand Delivery	<input type="checkbox"/> Overnight Courier
<input type="checkbox"/> Federal Express	<input type="checkbox"/> Other
<input checked="" type="checkbox"/> Electronically	
Signature: <u>Becky Hall</u>	

BEFORE THE IOWA BOARD OF PHARMACY

Pharmacy License of)	Case No. 2012-52
BAUDER PHARMACY, INC.)	
License No. 222,)	SETTLEMENT AGREEMENT
Respondent.)	& FINAL ORDER
)	

COME NOW the Iowa Board of Pharmacy and Bauder Pharmacy, Inc. (hereinafter, “Respondent”), pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), and enter into the following Settlement Agreement and Final Order settling a licensee disciplinary proceeding currently pending before the Board.

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

1. Respondent is a pharmacy operating in Des Moines, Iowa.
2. Respondent’s pharmacy license is active, but has been on indefinite probation since April 5, 2013.
3. On September 29, 2014, the State filed a Motion for a New Statement of Charges concerning the Respondent and a Proposed Statement of Charges.
4. On October 16, 2014, the Board granted the State’s motion and issued a Statement of Charges against the Respondent.
5. Respondent and the Board have reached a compromise settlement of the claims brought by the Board. Respondent chooses not to contest the allegations set forth 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. In order to resolve the Statement of Charges, Respondent agrees as follows:

a. Within thirty (30) days of the Board's approval of this Settlement Agreement and Final Order, Mark Graziano will divest himself of his ownership interest in the Respondent Pharmacy. Upon proof of divestment and application for licensure, the Board will issue Respondent a new pharmacy license in the name of the new owner/s—provided that Respondent's application comply with Iowa law. If Respondent fails to comply with this provision, the Board under the authority of Iowa Code section 155A.15(2)(c) may refuse to issue a renewal of Respondent's license.

b. Within thirty (30) days of the Board's approval of this Settlement Agreement and Final Order, the Respondent will construct a secure, physical barrier separating the Respondent's pharmacy department from the remainder of the business. This secure barrier shall meet the requirements set forth in Iowa Administrative Code rules 657-6.7 and 657-8.5(3). Board compliance officers shall verify compliance.

c. Upon the Board's approval of this Settlement Agreement and Final Order, the Respondent pharmacy shall be immediately inspected by Board compliance officers. Respondent's pharmacist-in-charge and consultant shall work with Board compliance officers to ensure any deficiencies are remedied within thirty (30) days.

d. Respondent shall comply with the terms of its probation set forth in the Board's April 5, 2013 Decision and Order and reaffirmed in its Decision and Order following remand from the district court. Respondent and Respondent's pharmacist-in-charge shall work with Board compliance officers and the consultant to ensure compliance with the terms of Respondent's probation.

e. Respondent shall be prohibited from applying for a Controlled Substances Registration for three (3) months from the date of the Board's approval of this Settlement Agreement and Final Order. Respondent may only apply for a Controlled Substances Registration if: (1) it is in compliance with the terms of its probation, (2) has successfully passed the inspection referenced in subparagraph (c) and a second inspection upon application, and (3) a new pharmacist-in-charge is appointed prior to application and said PIC agrees to remain as PIC for nine months after the grant of a Controlled Substances Registration. The decision to grant or deny the Respondent's Controlled Substances Registration remains in the full discretion of the Board.

f. Respondent shall be prohibited from engaging in sterile compounding until such time as it passes a USP 797 inspection by a Board-approved inspector/s or inspection agency.

g. Respondent agrees to dismiss with prejudice the judicial review of the Board's prior disciplinary order, Iowa Supreme Court Case Number 14-0987.

h. The terms of Respondent's probation and this settlement agreement survive the change in ownership and issuance of a new pharmacy license to the Respondent.

7. Should Respondent violate or fail to comply with any of the terms and conditions of this Settlement Agreement and Final Order, the Board—in addition to the penalty described in paragraph a—may initiate action to revoke or suspend Respondent’s Iowa pharmacy license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and Iowa Administrative Code 657 chapter 36.

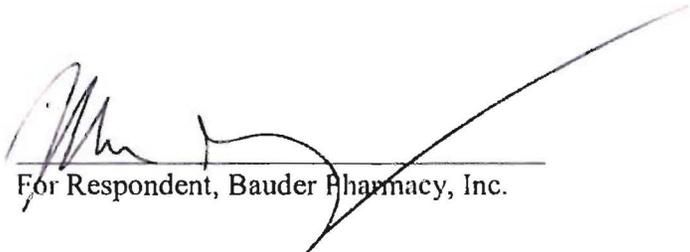
8. This Settlement Agreement and Final Order is the resolution of a contested case. By entering into this Settlement Agreement and Final Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Settlement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

9. The State's legal counsel may present this Settlement Agreement and Final Order to the Board *ex parte*.

10. This Settlement Agreement and Final Order 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 the Board or Respondent. If the Board approves this Settlement Agreement and Final Order, it shall be the full and final resolution of this matter.

11. The Board’s approval of this Settlement Agreement and Final Order shall constitute a **FINAL ORDER** of the Board. As a final order, this Settlement Agreement is a public document available for inspection under Iowa Code chapter 22.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 21 day of October 2014.



For Respondent, Bauder Pharmacy, Inc.

By this signature, Mark Graziano acknowledges s/he is the Representative for Respondent Bauder Pharmacy, Inc. and is authorized to sign this Settlement Agreement and Final Order on behalf of Respondent.

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the 28th day of October 2014.



EDWARD MAIER, R.Ph.
Chairperson, Iowa Board of Pharmacy

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

Rick L. Olson
2635 Hubbell Ave.
Des Moines, IA 50317
ATTORNEY FOR RESPONDENT

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

IN THE MATTER OF)	
)	
Pharmacy License of)	NOTICE OF INTENT
BAUDER PHARMACY, INC.)	TO DENY
License No. 222)	

TO: Bauder Pharmacy, Attention Pharmacist-in-Charge, Kim R. Robertson

YOU ARE HEREBY NOTIFIED that on December 10, 2014, the Iowa Board of Pharmacy met and voted to deny the issuance of a new or renewal pharmacy license to Bauder Pharmacy. Bauder Pharmacy shall cease doing business as a pharmacy in Iowa effective January 1, 2015. The intent to deny license is based upon the following:

LEGAL GROUNDS

Bauder Pharmacy was issued Iowa general pharmacy license number 222 on December 5, 2013. This license will expire on December 31, 2014. Pursuant to the authority of Iowa Code section 155A.15(2)(c), the Board may refuse to issue a new license to Bauder's pharmacy or renew its existing license. This refusal is based upon Bauder Pharmacy's continuing noncompliance with Board disciplinary orders, Iowa pharmacy law, and Board administrative rules. In addition to this Notice of Intent to Deny, the Board may also initiate further disciplinary action to revoke or suspend Bauder's pharmacy license or to impose other licensee discipline as authorized by Iowa Code chapter 272C and 155A and Iowa Administrative Code 657 chapter 36.

FACTUAL CIRCUMSTANCES

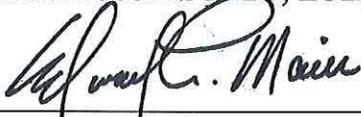
On October 28, 2014, the Board approved a Settlement Agreement and Final Order (Case No. 2012-52) (Board Order) for Bauder Pharmacy Inc., pharmacy license number 222. Paragraph 6(a) of the Order required Mark Graziano to divest himself of his ownership interest in Bauder Pharmacy no later than November 27, 2014. Upon proof of divestment, Bauder Pharmacy was to file an application for a new pharmacy license in the name of the new pharmacy owners. The Board Order provided that if Bauder Pharmacy failed to comply with this provision, the Board could refuse to issue a renewal of Bauder's pharmacy license. In addition, the Board Order required Bauder Pharmacy to construct a secure, physical barrier separating the pharmacy department from the remainder of the business. This barrier was to be in place no later than

November 27, 2014. On December 5, 2014, two Board compliance officers inspected Bauder Pharmacy and determined that no physical barrier had been constructed. Pharmacist in charge Kim Robertson indicated to the compliance officers that she did not agree that a barrier was needed. Bauder Pharmacy's consultant, Thomas Crabb, failed to work with Board compliance officers and Kim Robertson to ensure compliance with the Board Order. Furthermore, no proof of ownership divestment by Mark Graziano was provided to the Board. As of December 10, 2014, Bauder Pharmacy has not filed an application for a new pharmacy license in the name of new owners.

NOTICE OF APPEAL RIGHTS

Pursuant to the provisions of Iowa Administrative Code rule 657-36.16 you may appeal the Board's Notice of Intent to Deny by serving a notice of appeal and request for hearing upon the board not more than thirty 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 Iowa Administrative Code rules 657-35.19 and 657-36.8. If an appeal is not filed within this time period, this Notice of Intent to Deny licensure will become final.

Dated: December 10, 2014



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

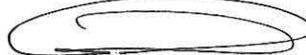
PROOF OF SERVICE

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 _____ | <input type="checkbox"/> other _____ |

on the 16 day of December, 2014.

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



Andrew Funk, R.Ph.
Compliance Officer

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:) BOARD ORDER GRANTING
) RENEWAL APPLICATION FOR
Pharmacy License of) PHARMACY LICENSE NO. 222,
BAUDER PHARMACY, INC.) SUBJECT TO ADDITIONAL¹
License No. 222) CONDITIONS OF PROBATION

On December 10, 2014, the Iowa Board of Pharmacy (Board) issued a Notice of Intent to Deny the issuance of a new or renewal pharmacy license to Bauder Pharmacy, Inc. Bauder Pharmacy filed a timely Notice of Appeal and Request for Hearing. A hearing was held on March 11, 2015 before the following members of the Board: Edward Maier, Chairperson; James Miller; Edward McKenna; Sharon Meyer; and LaDonna Gratias. The state was represented by Assistant Attorneys General Meghan Gavin and Laura Steffensmeier. Bauder Pharmacy, Inc. was represented by attorneys Guy Cook and Adam Zenor. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1) and 657 IAC 36.4, at the election of Bauder Pharmacy, Inc.

THE RECORD

The record includes the testimony of Andrew Funk, Kim Robertson, Chris Gage, and Thomas Suttie. The record also includes State Exhibits 1-16 and Bauder Pharmacy Exhibits 1-23.

FINDINGS OF FACT

Licensing and Disciplinary Background

Bauder Pharmacy, Inc. is the corporate owner of a pharmacy business and an ice cream business, which are operated under the business name of "Bauder Pharmacy" from a single retail location at 3802 Ingersoll Avenue in Des Moines, Iowa. There has been a pharmacy at this location since 1925. The pharmacy was originally operated by pharmacist Carolyn Bauder, and pharmacist Charles Graziano joined her as a partner in 1947. Charles Graziano and his wife, Corrine Graziano, later purchased the entire

¹ The terms of indefinite probation established in the Board's November 5, 2013 Decision and Order issued on November 5, 2013 remain in full force and effect.

pharmacy business in 1963. Members of the Graziano family have been the owners and operators of Bauder Pharmacy since that time. After Charles Graziano passed away, Bauder Pharmacy was jointly operated by two of his children, Mark Graziano and Kim Graziano Robertson, both of whom were licensed pharmacists. Bauder Pharmacy, Inc. was owned by Mark Graziano (majority owner), Kim Graziano Robertson, and Corrine Graziano. Corrine Graziano owns the building where Bauder Pharmacy is located. (Testimony of Kim Robertson; Bauder Exhibit 15)

Bauder Pharmacy and Mark Graziano have a significant disciplinary history with this Board. An inspection of Bauder Pharmacy on March 16, 2012 found 27 areas of non-compliance with Board rules. On May 10, 2012, the Board issued an immediate suspension of Bauder Pharmacy's controlled substance registration. Mark Graziano was the pharmacist-in-charge of Bauder Pharmacy at that time, and Kim Robertson was a full-time staff pharmacist. (State Exhibit 5; Testimony of Kim Robertson)

On April 5, 2013, the Board issued initial Findings of Fact, Conclusions of Law, Decision and Order against Bauder Pharmacy, Inc. and Mark Graziano in Case No. 2012-52. The Board's Decision and Order found approximately 20 violations against Mark Graziano, who at the time was the 68% owner of Bauder Pharmacy, Inc. Numerous violations were also found against Bauder Pharmacy. Following a limited remand from the district court, the Board's initial order was upheld in its entirety on November 5, 2013, with only minor factual amendments. (State Exhibits 15, 16)

The Board's Decision and Order in Case No. 2012-52 permanently revoked the pharmacist license of Mark Graziano, revoked the controlled substance registration issued to Bauder Pharmacy, Inc., and issued a Citation and Warning to Bauder Pharmacy, Inc. for the violations established in the Decision and Order. In addition, the Decision and Order placed the pharmacy license issued to Bauder Pharmacy, Inc. (number 222) on indefinite probation. In part, the terms and conditions of indefinite probation:

- required Bauder Pharmacy, Inc. to pay a \$25,000 civil penalty within 30 days;
- prohibited Bauder Pharmacy from performing any sterile compounding, unless otherwise ordered and approved by the Board;
- required Bauder Pharmacy to submit a written plan of action for correcting all remaining deficiencies; to submit policies and procedures for all operations of the pharmacy; and to submit a Quality Control Improvement (CQI) plan. These documents were to be submitted for Board approval within 30 days of the Board's Decision and Order;

- required Bauder Pharmacy to obtain Board approval for every pharmacist in charge of the pharmacy; and
- required quarterly inspections of Bauder Pharmacy to be conducted by a Board approved consultant at the pharmacy's expense, in order to ensure full compliance with the rules governing pharmacy practice. The consultant was required to submit quarterly reports to the Board not later than March 5, June 5, September 5, and December 5 of each year of the indefinite probation. The pharmacy was required to comply with all recommendations made by the consultant.

(State Exhibit 16)

The terms and conditions of probation also specified that: "Mark Graziano shall be allowed no access to the pharmacy department or to prescription drugs within the pharmacy." (State Exhibit 16, p. 44)

The United States Department of Justice conducted a two-year investigation into the diversion of controlled substances at Bauder Pharmacy. On September 24, 2014, Mark Graziano was indicted by a federal grand jury on 16 counts of Conspiracy to Distribute Controlled Substances and on two counts of Tax Evasion. On October 15, 2014, Assistant United States Attorney Kevin E. VanderSchel issued a letter to Attorney J. Keith Rigg stating that the federal investigation showed no involvement by Kim Robertson in the drug diversion of controlled substances at Bauder Pharmacy and that the government has concluded that Kim Robertson was the victim of her brother's manipulation of the pharmacy's financial records, as alleged in the wire fraud counts of the indictment returned by the grand jury. Mr. VanderSchel advised Mr. Rigg to feel free to share his letter with any person, company or agency that may believe that Kim Robertson was, or is, the subject of the federal investigation. (Bauder Exhibits 14, 20)

On October 20, 2014, the Board issued a Corrected Notice of Hearing and Statement of Charges against Bauder Pharmacy, Inc., which alleged four counts: Unethical Behavior or Practice Harmful or Detrimental to the Public, Having an Owner Who Has Violated Iowa Code Chapter 155A and Board Rules, Violation of a Board Order in a Disciplinary Case, and Failure to Maintain Security. The Factual Circumstances cited by the Board in support of these charges state, in part, that:

- Mark Graziano was listed as an owner of the pharmacy on the December 5, 2013 pharmacy license renewal;
- Mark Graziano continued to have access to the pharmacy department, including having keys and the alarm code for the pharmacy;

- no secure, physical barrier exists between the pharmacy department and the drug store/soda fountain;
- Bauder Pharmacy had only submitted two of the six required quarterly reports to date; and
- other requirements of the Board's Order, including submission of a corrective action plan, Continuous Quality Improvement plan, and payment of the \$25,000 civil penalty were not completed in a timely manner.

(State Exhibit 15)

On October 28, 2014, Bauder Pharmacy, Inc. and the Board entered into a Settlement Agreement and Final Order, in resolution of the October 20, 2014 charges. Mark Graziano signed the Settlement Agreement and Final Order as the representative for Bauder Pharmacy, Inc. By signing the Settlement Agreement and Final Order, Bauder Pharmacy, Inc. chose not to contest the allegations in the Statement of Charges and waived any objections to the terms of the Settlement Agreement and Final Order. Bauder Pharmacy, Inc. also agreed to dismiss with prejudice the judicial review of the Board's prior disciplinary order. (State Exhibit 6, pp. 16-19)

Pursuant to the signed Settlement Agreement, Bauder Pharmacy, Inc. agreed, in relevant part, that:

- Within 30 days of Board approval of the Settlement Agreement and Final Order, Mark Graziano will divest himself of his ownership interest in Bauder Pharmacy, Inc. Upon proof of divestment and application for licensure, the Board will issue a new pharmacy license in the name of the new owner/s, provided the application complies with Iowa law. If Bauder Pharmacy, Inc. fails to comply with this provision, the Board may refuse to issue a renewal of the pharmacy license under the authority of Iowa Code section 155A.15(2)(c);
- Within 30 days of Board approval of the Settlement Agreement and Final Order, Bauder Pharmacy, Inc. will construct a secure, physical barrier separating the pharmacy department from the remainder of the business. The secure barrier shall meet the requirements set forth in 657 IAC 6.7 and 8.5.² Board compliance officers shall verify compliance;

² 657 IAC 6.7 generally requires the pharmacist(s) on duty to be responsible for the security of the prescription department, including provisions for effective control against theft, diversion, or unauthorized access to prescription drugs. 657 IAC 8.5(3) pertains to the requirement of a secure barrier that allows the pharmacy department to be closed and secured in the absence of a pharmacist, except as provided in subrules 6.7 and 7.6. To ensure secure closure, the pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department

- Respondent shall comply with the terms of its probation set forth in the Board's April 5, 2013 Decision and Order and reaffirmed in its Decision and Order following remand from the district court;
- The terms of Bauder Pharmacy, Inc.'s probation and this settlement agreement survive the change in ownership and issuance of the new pharmacy license.

The deadline for the divestment of ownership by Mark Graziano and for installation of the secure barrier was November 27, 2014. (State Exhibit 6; Testimony of Andrew Funk)

Non-Compliance With October 21, 2014 Settlement Agreement

The October 21, 2014 Settlement Agreement required an immediate inspection of Bauder Pharmacy by the Board's compliance officers. Board Compliance Officer Andrew Funk, who is a registered pharmacist, made several visits to Bauder Pharmacy to verify compliance with the Settlement Agreement. Mr. Funk conducted an inspection of Bauder Pharmacy on November 4, 2014 and found only a few minor deficiencies at that time. Mr. Funk testified that the deficiencies were promptly rectified by Kim Robertson and did not warrant disciplinary action. Mr. Funk also reviewed the pharmacy's current policies and procedures, which he described as adequate. (Testimony of Andrew Funk; Kim Robertson; State Exhibits 5, 7)

Mark Graziano has been present within the soda fountain area of Bauder Pharmacy during most of Mr. Funk's visits. At hearing, Kim Robertson testified that in the past two years, Mark Graziano has probably been present on Bauder's premises, running the day to day operation of the soda fountain and ice cream business, on a daily basis. (Testimony of Andrew Funk; Kim Robertson)

Andrew Funk and Compliance Officer James Wolfe visited Bauder Pharmacy the morning of December 5, 2014 to ensure that a physical barrier had been constructed to isolate the pharmacy department from the rest of Bauder Pharmacy's business activities. At this visit, Compliance Officers Funk and Wolfe noted that construction of a secure barrier had not yet begun. Mr. Funk spoke to Kim Robertson, who was the designated pharmacist-in-charge. Ms. Robertson questioned the need for the secure barrier because Bauder Pharmacy is only open when a pharmacist is present.

is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent.

Ms. Robertson told Funk that other independent pharmacies were not required to have a security gate and that she felt that Bauder Pharmacy was being "singled out" by the Board with this requirement. (Testimony of Andrew Funk, Kim Robertson; State Exhibits 5, 7)

When asked if Mark Graziano had divested his ownership interest in Bauder Pharmacy, Ms. Robertson responded that it had been "taken care of" and that his ownership interest had been transferred to her. Ms. Robertson conceded, however, that she had not yet filed this information with the Board and had not yet filed a new pharmacy application. (Testimony of Andrew Funk; State Exhibit 5)

The afternoon of December 5, 2014, Kim Robertson emailed Andrew Funk and reported that a security company had advised her to install a locking gate to secure off the pharmacy area from the front of the store at the time of closing. Mr. Funk asked Robertson if she could describe the gate and she responded: "They said to run a security gate in front of pharmacy section to pull shut and lock upon closing to secure off the pharmacy area." Robertson emailed Funk a 1.25" x 1.5" example photo of the gate. On Sunday, December 7, 2014, Mr. Funk responded to Robertson by email and wrote: "From the picture, this appears to be an acceptable solution. Is there a rear entrance to the building? If so, there would need to be an additional gate at the rear of the pharmacy as well." Ms. Robertson responded that there were rear doors that cannot be accessed from the outside and can only be used as exit doors. There is no evidence in the record of any further response from Andrew Funk. Ms. Robertson interpreted Funk's email to constitute his approval of the gate that she intended to install. (Testimony of Andrew Funk; Kim Robertson; State Exhibits 7, 8; Bauder Exhibit 3)

As of December 8, 2014, the Board had not received any documentation of the divestment of Mark Graziano's ownership in Bauder Pharmacy nor had it received a new license application from Kim Robertson and Bauder Pharmacy. On December 8, 2014, Assistant Attorney General Gavin sent an email to Bauder's attorneys and its pharmacy consultant. AAG Gavin reminded them that it had been 40 days since the approval of the Settlement Agreement and that the Board had not received proof of Mark Graziano's divestment of ownership and had not received a license application from the new owners. The email further noted that Bauder had not yet complied with the secure barrier requirement, although they had submitted plans for the barrier. This was apparently in reference to the December 5, 2014 emails between Andrew Funk and Kim Robertson. One of Bauder's attorneys responded to AAG Gavin's December 8 email stating: "Divestment has occurred. Paperwork will be supplied to you (perhaps yet today, or tomorrow)." The email further stated that the security gate had to be approved by Inspector Funk prior to the order, that Inspector Funk authorized the gate

on Sunday, December 7, that the gate had been ordered that day, and that it would be installed the day it arrived. (Testimony of Andrew Funk; Bauder Exhibit 2; State Exhibit 5)

As of December 10, 2014, the Board still had not received proof of ownership divestment by Mark Graziano, and Bauder Pharmacy still had not filed a new pharmacy application in the names of the new owners. On December 10, 2014, the Board issued its Notice of Intent to Deny the issuance of a new or renewal application to Bauder Pharmacy. The Notice of Intent to Deny was based on Bauder Pharmacy's failure to comply with the terms of the Settlement Agreement by providing proof of divestment of ownership by Mark Graziano, by filing a new pharmacy application in the names of the new owners, and by constructing a secure, physical barrier separating the pharmacy department from the remainder of the business. (State Exhibit 1)

On December 10, 2014 at 2:06 p.m., a legal assistant to Bauder's attorneys sent a copy of the Special Meeting of Shareholders of Bauder Pharmacy, Inc. to AAG Gavin by email. (Bauder Exhibit 7 p. 1) The Minutes of the Special Meeting of Shareholders states that the meeting was held on November 22, 2014 at the office of Bauder Pharmacy, Inc., that all shareholders were present or being represented, and that Kim Robertson acted as Chairman of the meeting. The minutes further state that the following resolution was unanimously adopted:

BE IT RESOLVED: All the shares held by Mark Graziano will be gifted to Kim Robertson.

If Mark Graziano can find his shares, he will sign them over to Kim Robertson.

BE IT FURTHER RESOLVED, the next reporting requirement to the Iowa Secretary of State, Kim Robertson will be responsible for filing the report showing Mark Graziano has no interest in Bauder Pharmacy, Inc. nor holds any offices, and will register Kim Robertson as registered agent.

BE IT FURTHER RESOLVED, that Kim Robertson was unanimously elected to the following offices:

President

Vice-President

Treasurer

BE IT FURTHER RESOLVED, that Corrine R. Graziano, will continue to be the Secretary.

BE IT FURTHER RESOLVED, that Bauder's Ice Cream was not part of this transaction and Bauder's Ice Cream will remain with Mark Graziano.

(Bauder Exhibits 2, 6; State Exhibit 3)

Kim Robertson also signed a Statement of Change of Registered Office and/or Registered Agent for Bauder Pharmacy, Inc. The month (November) and year (2014) were typed on the form, and the day of the month (22) was handwritten. The form was later filed with the Iowa Secretary of State on December 29, 2014. (Bauder Exhibit 6A)

On December 15, 2014, the Board received an Application for Iowa Pharmacy License from Bauder Pharmacy, Inc. for the license period from January 1, 2015 through December 31, 2015. The application was signed by Kim Robertson as the President of Bauder, Inc. The application states that Bauder Pharmacy, Inc.:

- is open seven days a week (Monday-Friday, 8:30-6:00); Saturday 9:00-3:00, and Sunday (10:00-2:00);
- is owned by Kim Robertson (who is its President, Vice-President, and Treasurer) and by Corrine Graziano (who is the Secretary);
- currently employs two pharmacists: Kim Robertson, License No. 15845, who works an average of 50+ hours per week, and Chris Gage, License No. 15016, who works an average of 4 hours per week;
- currently employs three Pharmacy Support Staff, who work 25 hours, 15 hours, and 15 hours per week on average; and
- is on probation and dispenses only non-narcotic legend drugs and is awaiting reinstatement of its DEA license.

The application further indicated that owner Kim Graziano has pending charges before a licensing authority and that Mark Graziano has a felony, has had his license revoked, and has been removed from corporate ownership. (State Exhibit 2)

On December 22, 2014, Bauder Pharmacy, Inc. filed a Notice of Appeal and Request for Hearing on the Board's Notice of Intent to Deny License. In its Notice of Appeal, Bauder Pharmacy stated that:

- there had been procedural hurdles to the installation of the physical barrier, which was now "underway." Bauder Pharmacy attached copies of correspondence with Andrew Funk as well as the Order Confirmation for the Physical Barrier. (State Exhibit 3; Bauder Exhibits 3, 4, 9)
- Mark Graziano's divestment of his Bauder ownership "was timely and was thereafter provided to the Board." Bauder Pharmacy attached the Minutes of Special Meeting of Shareholders to the Notice of Appeal. (State Exhibit 3; Bauder Exhibit 6); and

- the application for a new pharmacy license had been filed on or about December 11, 2014 along with the requisite fee payment. (State Exhibit 3; Bauder Exhibit 8).

The confirmation order for the security gate and the email correspondence between Mark Graziano and Steve May of Cisco-Eagle (the manufacturer of the security gate) established that the gate was ordered by Mark Graziano on December 10, 2014, which was 13 days after the deadline established in the Settlement Agreement for the physical barrier to be installed. The confirmation order further indicates that the cost of the gate (\$2,940.49) was paid for with a Bauder Pharmacy credit card issued in the name of Mark Graziano. The emails indicate that there was a delay in shipping the gate because the factory was closed for holiday break. (Bauder Exhibits 3, 4, 9; State Exhibit 11)

The security gate was eventually installed at Bauder Pharmacy on Saturday, January 17, 2015, which was 51 days after the November 27, 2014 deadline. On January 20, 2015, Kim Robertson sent an email to Andrew Funk informing him that the gate had been installed. Mr. Funk responded that he would be stopping by sometime that week to inspect the security gate and take some photos. (State Exhibit 7, p. 22)

On January 21, 2015, Andrew Funk visited Bauder Pharmacy to inspect the security gate and to take photos of it. Kim Robertson was the pharmacist on duty at the time of the inspection, and she demonstrated the gate's operation for Mr. Funk. There are two gates that fold out on tracks attached to the ceiling and the floor. The two gates are then secured with a padlock. Ms. Robertson reported that only she and staff pharmacist Chris Gage have keys to the padlock. Mr. Funk determined that the materials used to construct the gate were sufficient to satisfy the strength requirements of 657 IAC 8.5(3). Although there were gaps in the gate large enough for an arm to pass through, only over the counter vitamins and no prescription medications could be reached by an arm when the gate was closed. (Testimony of Andrew Funk; State Exhibits 7, 9)

Mr. Funk had concerns about the gate's placement because it failed to completely separate the pharmacy department from the ice cream fountain business. Specifically, the booths for lunch patrons, the ice cream prep-area, and the walk-in freezer were located within the area secured by the gate. In order to enter these work areas for the ice cream business, a person would have access to the secured pharmacy department. (Testimony of Andrew Funk; State Exhibits 7, 9, 10)

On January 26, 2015, Andrew Funk returned to Bauder Pharmacy with Compliance Officer Jim Wolfe to obtain his opinion concerning the adequacy of the security gate that had been installed on January 17, 2015. During this visit, Kim Robertson

demonstrated the security gate for Mr. Wolfe, and Mr. Funk videotaped the demonstration. During the demonstration, Ms. Robertson continued to question why it was necessary for Bauder Pharmacy to install the security barrier. At the time of this inspection, Mark Graziano was present in the soda fountain area of Bauder Pharmacy and was video recording the interaction between Robertson and Wolfe. (State Exhibits 7, 12; Testimony of Andrew Funk)

Compliance Officer Wolfe observed that the Settlement Agreement specifically stated that "Respondent will construct a secure, physical barrier separating the Respondent's pharmacy department from the remainder of the business." Wolfe noted that the constructed barrier separates the front of the store from the rear of the store but only partially separates the two businesses. The pharmacy department, as designated by the security gate, also includes the ice cream freezer, the ice cream preparation area, and the booths for customers of the soda fountain. He further noted that Mark Graziano continued to have access to the pharmacy department and continued to provide direction to Kim Robertson regarding the business of the pharmacy. The current gate served no purpose during business hours and does not separate the two businesses to allow them to operate independently of one another. In order to separate the two businesses and comply with the Settlement Agreement, Mr. Wolfe suggested that a secure barrier be constructed with a lockable glass enclosure (top of the pharmacy counter to the ceiling or header with track) surrounding the entire front and sides of where prescription drugs are kept, with a sturdy lockable door on the side. For added security, a wraparound gate could be utilized during the closed hours of the pharmacy, in addition to the glass enclosure. (State Exhibit 7, pp. 22-23; State Exhibits 9, 10; Testimony of Andrew Funk)

On February 20, 2015, Mark Graziano entered a guilty plea to two federal felonies: one count of Conspiracy to Distribute Controlled Substances and one count of Tax Evasion. The remaining 16 counts were dismissed as part of a plea agreement. Mark Graziano was sentenced to 24 months of incarceration in a federal correctional institution on both counts, to be served concurrently. Upon his release from imprisonment, Mr. Graziano will be on supervised release for a term of three years. He was also required to pay restitution totaling \$577,505 to the Internal Revenue Service and to the Iowa Department of Revenue. Mr. Graziano has been ordered to report to the United States Marshall's Office on March 26, 2015 to begin his two year term of incarceration. According to Ms. Robertson, the federal judge recognized that she would need Mark Graziano's help in preparing to assume responsibility for all of the Bauder Pharmacy business functions during his incarceration. Ms. Robertson testified that while Mark has had no role in the pharmacy department since the revocation of his license, he has continued to be solely responsible for most of the Bauder Pharmacy ice cream business,

including its state fair booth, and for Bauder Pharmacy's banking. (Bauder Exhibits 12, 20, 22; Testimony of Kim Robertson)

As of February 26, 2015, Mark Graziano was still listed as the President of Bauder Pharmacy, Inc. on the Iowa Secretary of State's website. (State Exhibit 14) A printout from the Secretary of State's website, however, shows that the list of officers for Bauder Pharmacy, Inc. no longer included Mark Graziano as of March 10, 2015. "Kim Graziano" is now listed as the President and Treasurer of Bauder Pharmacy, Inc. and Corrine Graziano was listed as the Secretary. (Bauder Exhibit 21)

Thomas Crabb, who is both a licensed pharmacist and a lawyer, has been serving as the Board approved consultant for Bauder Pharmacy. The record includes Mr. Crabb's March 5, 2015 Consultant Quarterly Report of Compliance. This report states that the pharmacy was in compliance with items A through G of the Board's April 5, 2013 Order. Mr. Crabb's report states that he had been "informed" that the paperwork for Mark Graziano's divestiture was complete and had been submitted to the Board as requested. Mr. Crabb's report further stated that Ms. Robertson had informed him that the locks and security system codes have been changed and that Mark Graziano does not have a key or the security code. (Testimony of Kim Robertson; Bauder Exhibits 11, 19)

If the Board determines that Bauder Pharmacy must have a new pharmacy consultant, Kim Robertson is willing to name Thomas G. Suttie as the pharmacy's new consultant, and Mr. Suttie is willing to serve in this capacity. Thomas G. Suttie has over 39 years of experience in retail and hospital pharmacies and has never been subject to any license discipline. (Testimony of Kim Robertson; Thomas Suttie; Bauder Exhibit 18)

Chris Gage has been employed by Bauder Pharmacy as a part-time pharmacist since November 2012. When he was first hired, Mr. Gage was working approximately 30 hours per week but has recently been working on an "as needed" basis. Mr. Gage has 38 years of experience as a pharmacist, including experience as a compounding pharmacist, as a retail pharmacist, as a pharmacy owner, and as a pharmacist-in-charge. Mr. Gage's pharmacist license has never been subject to discipline. Kim Robertson testified that she would be willing to name Chris Gage as the pharmacist-in-charge of Bauder Pharmacy if the Board determines that a change of the pharmacist-in-charge is necessary. Mr. Gage is willing to assume the role of pharmacist-in-charge of Bauder Pharmacy. (Testimony of Kim Robertson; Chris Gage; Bauder Exhibit 17)

CONCLUSIONS OF LAW

Iowa Code section 155A.15(2)(c)(2013) provides, in relevant part, that the Board may refuse to issue or renew a license if the Board finds that the applicant or licensee has violated any provision of Iowa Code chapter 155A or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of Iowa Code chapter 155A or any rule adopted under this chapter. 657 IAC 36.1(4)(i) specifically authorizes the Board to discipline a licensee for violating a lawful order of the board in a disciplinary hearing.

The October 28, 2014 Settlement Agreement and Final Order resolved the Statement of Charges filed against Bauder Pharmacy, Inc. on October 20, 2014 and constitutes a lawful order of the board in a disciplinary hearing. Moreover, the Settlement Agreement and Final Order provided that if Respondent violated or failed to comply with the terms and conditions of the Settlement Agreement and Final Order, the Board may refuse to issue a renewal of Respondent's pharmacy license, pursuant to Iowa Code section 155A.15(2)(c), or may take action to revoke, suspend, or take other disciplinary action against the pharmacy license, as authorized by Iowa Code chapters 155A, 272C and 657 IAC chapter 36.

The preponderance of the evidence in this record established that Bauder Pharmacy, Inc. failed to comply, in a timely manner, with all of the terms and conditions of the October 28, 2014 Settlement Agreement and Final Order. The Settlement Agreement and Final Order required Mark Graziano to divest himself of his ownership interest in Bauder Pharmacy, Inc. by November 27, 2014. It further required Bauder Pharmacy, Inc. to provide proof of Mr. Graziano's divestment of ownership and to file an application for a pharmacy license in the name(s) of the new owners. Representatives of Bauder Pharmacy, Inc. were reminded of these requirements on December 5, 2014 and again on December 8, 2014.

Although Ms. Robertson verbally informed Andrew Funk on December 5, 2014 that Mark Graziano had divested his ownership interest in Bauder Pharmacy, she did not state when this occurred and did not provide any documentation of the ownership transfer. Documentation of divestment of Mr. Graziano's ownership was not received by the Board until after the Notice of Intent to Deny was issued on December 10, 2014. The documentation consisted of Minutes of a November 22, 2014 Special Meeting of the three shareholders of Bauder Pharmacy, Inc. The Minutes were signed by all three shareholders and state, in part: "All the shares held by Mark Graziano will be gifted to Kim Robertson. If Mark Graziano can find his shares, he will sign them over to Kim Robertson." The Minutes further state that "Bauder's Ice Cream was not part of this

transaction and Bauder's Ice Cream will remain with Mark Graziano." The Board has been given no explanation for the 18 day delay in providing this documentation if in fact the divestment occurred on November 22, 2014 as stated in the Minutes. In addition, the new pharmacy license application was not submitted to the Board by Kim Robertson until December 15, 2014.

The Settlement Agreement and Final Order further required the construction of a "secure, physical barrier separating the pharmacy department from the remainder of the business." The barrier was to be constructed no later than November 27, 2014. Bauder Pharmacy, Inc. did not even order the barrier, which consists of a sliding gate that can be padlocked, until December 10, 2014. The gate was not installed until January 17, 2015. Upon inspection of the gate, it was apparent to the Board's Compliance Officers that significant portions of the ice cream business, i.e. the ice cream prep area and the walk-in freezer, were within the same physical area that is enclosed by the gate. By its design and placement, the gate is only to be closed and locked at the close of the business day and provides no separation of the pharmacy and ice cream business when Bauder Pharmacy is open.

By the terms of probation imposed on Bauder Pharmacy, Inc. in the Board's November 5, 2013 Decision and Order, Mark Graziano "shall be allowed no access to the pharmacy department or to prescription drugs within the pharmacy." The gate installed by Bauder Pharmacy does nothing to provide a secure separation of the pharmacy business and the ice cream business, which continues to be owned by Mark Graziano. As observed by the Board's Compliance Officer and testified to by Kim Robertson, Mark Graziano continued to be on the premises on an almost daily basis and to actively operate the Bauder Pharmacy ice cream business after his license as a pharmacist was revoked. Although Mr. Graziano will soon be incarcerated for two years, there is no reason to believe that he will not continue to own and operate the ice cream business upon his release from prison. The Board continues to have very serious concerns about the security of Bauder's pharmacy department given the co-location of pharmacy business with the ice cream business owned by Mark Graziano.

DECISION AND ORDER

IT IS THEREFORE ORDERED that the application for an Iowa Pharmacy License filed on behalf of Bauder Pharmacy, Inc. on December 15, 2014 is hereby GRANTED, subject to the following additional terms and conditions:

- A. Within 30 days of the issuance of this Order granting the pharmacy license, Bauder Pharmacy, Inc. shall name a new pharmacist-in-charge, who has

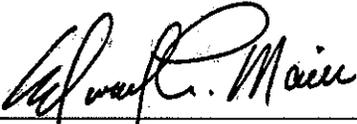
been pre-approved by the Board. Based on the presentation at hearing, the Board would approve Chris Gage as the new pharmacist-in-charge.

B. Within one (1) year of the issuance of this Order granting the pharmacy license, any business owned and/or operated by Mark Graziano, including Bauder Ice Cream, may no longer be co-located in the same retail space as the pharmacy department of Bauder Pharmacy, Inc.

C. Bauder Pharmacy, Inc. will be subject to random inspections by Board staff for its compliance with all requirements of the Board's November 5, 2013 Decision and Order and for its compliance with the requirements of this Order of the Board. The frequency of inspections will be determined by the Board, in its discretion.

The Board will not require Bauder Pharmacy, Inc. to retain a different pharmacy consultant and may continue to use Thomas Crabb as its Board-approved pharmacy consultant. Bauder Pharmacy, Inc. may retain a different consultant, so long as the consultant is Board-approved. The Board would approve Thomas Suttie as a pharmacy consultant.

Dated this 31st day of March, 2015.

A handwritten signature in cursive script, appearing to read "Edward Maier", written over a horizontal line.

Edward Maier, Chairperson
Iowa Board of Pharmacy

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.