BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

| | | |
|---|---|---|
| Re: Pharmacist License of **DWAYNE A. PLENDER** License No. 13561 Respondent | ) ) ) ) | **COMPLAINT AND STATEMENT OF CHARGES** |

**COMES NOW**, Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 4th day of December, 1989, and files this Complaint and Statement of Charges against Dwayne A. Plender, a pharmacist licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Rollin C. Bridge, Chairperson; Melba L. Scaglione, Vice Chairperson; Donna J. Flower; Marian L. Roberts; John F. Rode; Alan M. Shepley; and Gale W. Stapp are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent was issued a license to practice pharmacy in Iowa on January 28, 1969, by examination.

3. Respondent is self-employed as the owner and pharmacist in charge of the Dutch Mill Pharmacy located at 104 Albany Avenue N.E. in Orange City, Iowa.

4. Respondent currently resides at Rural Route 2, Orange City, Iowa 51041.

5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1991.

6. The Board has received investigative reports dated January 3, 1989, and September 20, 1989, from Pharmacy Investigator Morrell A. Spencer. Those reports indicate the following:

a. Richard Thorne, M.D., discontinued his medical practice in Orange City on March 31, 1987, and moved to Glendive, Montana. Between April 1, 1987, and July 5, 1988, Respondent delivered controlled and non-controlled prescription drugs without legal authorization by creating and filling a total of 68 unauthorized new prescriptions (some with refills indicated and later dispensed by Respondent) which purported to be issued by Dr. Thorne for various patients. Of these 68 prescriptions, 59 were written for non-controlled prescription drugs, one was written for a schedule III controlled substance, five were

written for schedule IV controlled substances, and three were written for schedule V controlled substances.

b. Carl Vander Kooi, M.D., discontinued his medical practice in Orange City on May 23, 1988, and moved to Cedar Falls. Between June 1, 1988, and September 28, 1988, Respondent delivered controlled and non-controlled prescription drugs without legal authorization by creating and filling a total of 57 unauthorized new prescriptions (some with refills indicated and later dispensed by Respondent) which purported to be issued by Dr. Vander Kooi for various patients. Of these 57 prescriptions, 43 were written for non-controlled prescription drugs, two were written for schedule III controlled substances, and 12 were written for schedule IV controlled substances.

7. Respondent is guilty of violations of 1989 Iowa Code sections 155A.23(2), 155A.23(4), 204.308(3), 204.402(1)(a), and 204.403(1)(d) by virtue of the allegations in paragraph 6.

Iowa Code section 155A.23 provides, in part, the following:

> A person shall not:...
> 2. Willfully make a false statement in any prescription, report, or record required by this chapter.
> ....
> 4. Make or utter any false or forged prescription or written order.

Iowa Code section 204.308 provides, in part, the following:

> 3. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included 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.

Iowa Code section 204.402 provides, in part, the following:

> 1. It is unlawful for any person:
> a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 204.308.

Iowa Code section 204.403 provides, in part, the following:

> 1. It is unlawful for any person knowingly or intentionally:...
> d. To furnish false or fraudulent material information in, or omit any material information from,

any application, report, or other document required to be kept or filed under this chapter, or any record required to be kept by this chapter...

Iowa Code section 155A.12 provides, in part, the following:

> ...The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:
>
> 1. Violated any provision of this chapter or any rules of the board adopted under this chapter.
>
> ....
>
> 5. Violated any provision of the controlled substances Act or rules relating to that Act.

8. Respondent is guilty of violations of 657 Iowa Administrative Code sections 9.1(4)(c) and 9.1(4)(j) by virtue of the allegations in paragraph 6.

657 Iowa Administrative Code section 9.1 provides, in part, the following:

> 4. The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed $25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...
>
> c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful to the public. Proof of actual injury need not be established.
>
> ....
>
> j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

9. Respondent is guilty of violations of 21 Code of Federal Regulations sections 1306.03(a) and 1306.04(a) by virtue of the allegations in paragraph 6.

21 Code of Federal Regulations section 1306.03 provides, in part, the following:

> (a) A prescription for a controlled substance may be issued only by a individual practitioner who is:

(1) authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) either registered or exempted from registration pursuant to sections 1301.24(c) and 1301.25 of this chapter.

21 Code of Federal Regulations section 1306.04 provides, in part, the following:

> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

The Iowa Board of Pharmacy Examiners finds that paragraphs 7, 8, and 9 constitute grounds for which Respondent's license to practice pharmacy in Iowa can be suspended or revoked.

**WHEREFORE**, the undersigned charges that Respondent has violated 1989 Iowa Code sections 155A.23(2), 155A.23(4), 204.308(3), 204.402(1)(a), and 204.403(1)(d; 657 Iowa Administrative Code sections 9.1(4)(c) and 9.1(4)(j); and 21 Code of Federal Regulations sections 1306.03(a) and 1306.04(a).

**IT IS HEREBY ORDERED** that Dwayne A. Plender appear before the Iowa Board of Pharmacy Examiners on January 9, 1990, at 2:00 o'clock p.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend or revoke the license to practice pharmacy issued to Dwayne A. Plender on January 28, 1969, and take whatever additional action that they deem necessary and appropriate.

Respondent may bring counsel to the hearing, may cross-examine

any witnesses, and may call witnesses of his own. The failure of Respondent to appear could result in the permanent suspension or revocation of his license. Information regarding the hearing may be obtained from Thomas D. McGrane, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319.

IOWA BOARD OF PHARMACY EXAMINERS

Norman C. Johnson
Executive Secretary

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

| | | |
|---|---|---|
| Re: Pharmacist License of | : | |
| **DWAYNE A. PLENDER** | : | **STIPULATION** |
| License No. 13561 | : | |
| Respondent | : | |

**WHEREAS**, Dwayne A. Plender, hereinafter referred to as the Licensee, has had certain allegations made against him by the Board of Pharmacy Examiners, hereinafter referred to as the Board, concerning his professional conduct as a pharmacist, and

**WHEREAS**, both the Licensee and the Board desire to arrive at a mutually agreeable informal settlement of this matter,

**IT IS MUTUALLY AGREED AND STIPULATED** as follows between the Licensee and the Board:

**1.** That the Board, through its representative Rollin C. Bridge, and the Licensee have entered into settlement discussions and have agreed upon a disposition of this matter.

**2.** That the Licensee desires to avoid the uncertainty and the expense of a trial and desires to consent to the disciplinary action to be taken by the Board as specified in paragraph 4, infra.

**3.** It is the purpose and intent of the parties hereto to waive all the provisions of Chapter 17A of the 1989 Code of Iowa as they relate to notice and hearing on the matter of revocation or suspension of Licensee's license to be a pharmacist, and to acknowledge that each are fully aware of their rights and procedures afforded them through Chapter 17A of the 1989 Code of Iowa and the rules of the Board of Pharmacy Examiners promulgated in accordance and pursuant thereto, particularly Section 17A.12 as it relates to contested cases and provides notice of hearing and records, and Section 17A.18 as it relates to the requirements concerning notice of the suspension and revocation of licenses.

**4.** It is the understanding of both the Licensee and the Board that they will enter into an Order and Consent to Order which will provide for the following:

**a.** Licensee shall pay a fine of $500.00 to the Board. A check in that amount, payable to the State of Iowa/Board of Pharmacy Examiners, shall be delivered to the Board office within 10 days of the signing of the attached Order and Consent to Order.

**b.** Licensee is placed on probation for a period of six months. The probationary period to begin effective with the signing of the attached Order and Consent to Order.

**c.** Licensee shall not supervise any registered intern nor perform any of the duties of a preceptor during the probationary period.

**d.** Licensee shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

**e.** Should Licensee leave Iowa to reside or practice outside this state, he shall notify the Board in writing of the date of departure and return. Periods of residency or practice outside the state shall not apply to a reduction in the probationary period.

**f.** Licensee shall report in writing no later than the 10th of each month his residency and employment status during the probationary period.

**THE ABOVE AND FOREGOING CONSTITUTE THE FULL AND COMPLETE STIPULATION AND AGREEMENT OF THE PARTIES HERETO.**

Rollin C. Bridge

Rollin C. Bridge, Chairperson
Iowa Board of Pharmacy Examiners

Dwayne Plender RPh

Dwayne A. Plender

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

| | | |
|---|---|---|
| Re: Pharmacist License of | : | **ORDER** |
| **DWAYNE A. PLENDER** | : | **AND** |
| License No. 13561 | : | **CONSENT TO ORDER** |
| Respondent | : | |

The Iowa Board of Pharmacy Examiners, having been advised of the allegations that Dwayne A. Plender has conducted himself in a manner which could cause his license to practice pharmacy to be suspended, and the Board of Pharmacy Examiners through a Board Member and said Dwayne A. Plender, having entered into a Stipulation representing their mutual informed consent as to the waiver of the provisions found in the Iowa Administrative Code appearing at Chapter 17A, particularly Section 17A.12 and Section 17A.18, Code of Iowa 1989, in regards to Notice and Hearing, the parties to this action agree to an informal settlement of this matter, namely that the license of Dwayne A. Plender be disciplined according to the conditions attached hereto.

**ORDER**

**IT IS THEREFORE ORDERED**, subject to the consent of Dwayne A. Plender to be contained herein to this Order that the license of Dwayne A. Plender to practice pharmacy be disciplined according to the conditions outlined in the Stipulation attached hereto and made part of this Order.

Date 1/9/90

Rollin C. Bridge

Rollin C. Bridge, Chairperson
Iowa Board of Pharmacy Examiners

**CONSENT TO ORDER**

I, Dwayne A. Plender, hereby consent to the Order set forth above, waive my right to a hearing in this matter, and thereby specifically waive a right to confrontation, cross-examination of witnesses, production of evidence, making of a record and judicial review.

Date 1/16/90

Dwayne Plender RPh

Dwayne A. Plender

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re: | ) | Case No. 2014-45 |
| Pharmacist License of | ) | |
| **DWAYNE PLENDER** | ) | **STATEMENT OF CHARGES** |
| License No. 13561, | ) | **& NOTICE OF HEARING** |
| Respondent. | ) | |

**COMES NOW** the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent was issued Iowa license 13561. Respondent's license is currently active.

## A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 6, 2015, before the Board. The hearing shall be held during the afternoon session, beginning at 1:00 p.m. and shall be located in the Board conference room located at 400 S.W. 8th Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on 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
### FAILURE TO VERIFY THE ACCURACY OF A PRESCRIPTION

Respondent is charged with failing to properly verify the accuracy of a prescription in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 6.10(1), 8.3(3) and 36.1(4)(*u*).

### Count II
### FAILURE TO COUNSEL A PATIENT ON A CHANGE IN DOSAGE

Respondent is charged with failing to counsel a patient on a change in dosage in violation of Iowa Code section 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 6.14(1) and 36.1(4)(*u*).

### Count III
### FAILURE TO NOTIFY BOARD OF A MALPRACTICE SETTLEMENT

Respondent is charged with failing to notify the Board of a malpractice settlement in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rule 36.1(4)(*p*).

## D. FACTUAL CIRCUMSTANCES

1. On March 20, 2014, the Board received a complaint about a dispensing error at Dutch Mill Pharmacy in Orange City, Iowa.

2. At all times relevant to the complaint, the Respondent, an Iowa-licensed pharmacist, served as a staff pharmacist at Dutch Mill Pharmacy.

3. On March 13, 2014, the pharmacy received an electronic prescription for lamotrigine for an eight-year-old patient. The patient had been taking 5mg chewable tablets (5 tablets, 2 times per day). The new prescription called for the patient to take 25mg tablets (1 tablet, 2 times per day).

4. On Friday, March 14, 2014, the patient's mother called the pharmacy to refill the prescription.

5. Respondent filled and verified the prescription. The patient's mother picked up the prescription on March 17, 2014. The prescription's label read: "Take 5 tablets 2 times per day." The label further noted that the tablets were 5mg chewable tablets. The patient was given 5 tablets on the evening of March 17th and 5 tablets on the morning of March 18th.

6. It was later discovered that the prescription was correctly filled with the 25mg tablets, but the label incorrectly provided instructions for the 5mg tablet. As a result, the patient took two dosages of 125mg instead of the prescribed 25mg.

7. The patient was reported ill by her school on March 18, 2014.

8. The patient's mother was not counseled on the change in dosage when picking up the prescription.

9. This dispensing error was not recorded in the pharmacy's Continuous Quality Improvement Program.

10. During the course of this investigation, it was discovered that in 2009 Respondent misfiled a prescription for tramadol. The patient was mistakenly given zolpidem. Due to the error, the patient experienced double vision, hallucinations, and incurred thousands of dollars in medical testing. Respondent's malpractice insurance settled with the patient in 2010 for $86,117.60.

11. This settlement was not reported to the Board.

## 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 19th day of November, 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

PROOF OF SERVICE

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

( ) personal service
(X) certified mail, return receipt requested
Article Number 91719999170310675798
( ) first class mail
( ) facsimile
( ) other _____

on the 19th day of November, 2014.

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

Debbie S. Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
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| IN THE MATTER OF: | ) | |
| | ) | Docket No. 2014-45 |
| Pharmacist License of | ) | DIA No. 14PHB054 |
| **BRENT PLENDER** | ) | |
| License No. 17651 | ) | |
| | ) | |
| Pharmacist License of | ) | |
| **DWAYNE PLENDER** | ) | |
| License No. 13561 | ) | |
| | ) | |
| Pharmacy License of | ) | |
| **DUTCH MILL PHARMACY** | ) | |
| License No. 445 | ) | **FINDINGS OF FACT,** |
| | ) | **CONCLUSIONS OF LAW,** |
| Respondents. | ) | **DECISION, AND ORDER** |
| | ) | |

## STATEMENT OF THE CASE

On November 19, 2014, the Iowa Board of Pharmacy (Board) found probable cause to file a Statement of Charges & Notice of Hearing against Respondents Brent Plender, Dwayne Plender, and Dutch Mill Pharmacy. The Statement of Charges alleges that Respondents Dwayne Plender and Dutch Mill Pharmacy: 1) failed to verify the accuracy of a prescription; 2) failed to counsel a patient on a change in dosage; and 3) failed to notify the Board of a malpractice settlement. Additionally, the Statement of Charges alleges that Respondent Dutch Mill Pharmacy failed to maintain a continuous quality improvement program. The Statement of Charges also alleges that Respondent Brent Plender violated the duties of a pharmacist-in-charge.

A hearing was held on April 28, 2015. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratias; Susan Frey; Judith Trumpy; and Edward McKenna. Respondents appeared and were self-represented. Assistant attorney general Meghan Gavin represented the State. The hearing was closed to the public at the election of Respondents, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

## THE RECORD

The record includes the Notice of Hearing and Statement of Charges with regard to each of the three Respondents. The record also includes hearing testimony of Andrew Funk,

Brent Plender, and Dwayne Plender. The State introduced Exhibits 1 through 11, which were admitted as evidence. Respondents introduced Exhibits A through D, which were admitted as evidence.

## FINDINGS OF FACT

Respondent Dutch Mill Pharmacy holds Iowa pharmacy license number 445, which is currently active. Respondent Brent Plender holds Iowa pharmacist license number 17651, which is currently active. Respondent Dwayne Plender holds Iowa pharmacist license number 13561, which is currently active. At all times relevant to this action, Respondent Brent Plender was employed at Dutch Mill Pharmacy in Orange City, Iowa as pharmacist-in-charge. At all times relevant to this action, Respondent Dwayne Plender was employed at Dutch Mill Pharmacy as a pharmacist.[1]

*March 2014 Dispensing Error*

The Board received a complaint on March 20, 2014 regarding all three Respondents. The complaining party alleged that Dwayne misfilled a prescription for her daughter, eight year-old H.P., resulting in H.P. taking a dose that was five times the strength prescribed. Specifically, H.P. was prescribed lamotrigine for epilepsy. Previously, H.P. had been prescribed 5 milligram chewable tablets at a dosage of four pills twice a day, or 20 milligrams per dose. On March 13, 2014, H.P.'s health care provider sent an electronic prescription to Respondent Dutch Mill Pharmacy, which switched H.P. to a 25 milligram tablet to be taken two times per day. Because H.P. had been receiving chewable tablets previously, when the new prescription was received pharmacist Blake Plender changed the prescription in the pharmacy's electronic system to reflect that H.P. should receive five 5 milligram chewable tablets twice per day. (Exh. 4, pp. 14-20, Exh. 8, p. 35).

Dwayne filled H.P.'s prescription on March 17. While Dwayne filled the pill bottle with 25 milligram tablets, the prescription label that he affixed to the bottle directed H.P. to take five 5 milligram tablets twice a day. There is a visual difference between the 5 and 25 milligram tablets; one is round and one is oblong. Dwayne acknowledged that he should have noticed the difference between the two tablets upon visual inspection. Effectively, the discrepancy between the label instructions and the dispensed dosage meant that in taking the tablets as directed, H.P. would get a 125 milligram dosage, or five times what she was actually prescribed. (Exh. 4, p. 20; D. Plender testimony).

H.P. took five of the 25 milligram tablets at bedtime on March 17 and again the following morning. At approximately 9:15 AM on March 18, H.P.'s school called to inform her mother that H.P. was experiencing nausea, dizziness, and vomiting. Based on her belief that the tablets she had given H.P. did not look the same as the 5 milligram chewable tablets she had previously been prescribed, H.P.'s mother called to ask the

[1] Respondent Dwayne Plender is the father of Respondent Brent Plender. Due to the two individual Respondents having the same last name, they will be referred to by first name throughout this decision.

pharmacy whether the prescription had been dispensed in error. She spoke with Respondent Brent Plender, who took some information from her regarding the pills. The pharmacy attempted to make contact with H.P.'s mother later that day; she ultimately spoke with pharmacist Blake Plender. Blake admitted that the pharmacy made an error in dispensing the medication; 25 milligram tablets were erroneously dispensed and H.P. was directed to take five for each dose. (Exh. 4, p. 20; Funk testimony).

Prior to this incident, the pharmacy used a visual verification system. Under this system, the pharmacist compared the National Drug Code (NDC) on the stock bottle to the NDC on the prescription to verify that the two matched.[2] At that point, the prescription was bagged and placed in a will call location to await patient pick-up. A small percentage of pharmacies in the state still use visual verification to check the accuracy of prescriptions. Electronic scan verification is not mandatory. (B. Plender, Funk testimony).

Since this incident and the resulting investigation, the pharmacy has implemented a scan verification system. Under this system, the pharmacist scans the stock bottle from which the prescription is being filled. The pharmacist then compares this information with an electronic image of the prescription. The pharmacist must electronically sign that verification has occurred. (Funk, B. Plender testimony).

When a misfill is reported to the Board through the complaint process, it is standard practice for the Board to request to see the pharmacy's continuous quality improvement (CQI) log. The purpose of the CQI process for pharmacies is to track errors, understand where in the process errors are occurring, and to improve policies and procedures through that knowledge. The Board reviewed the pharmacy's CQI report during its investigation and no errors were listed. (Funk testimony).

During the investigation, Brent acknowledged that the pharmacy has had errors in the past, including miscounts, where a patient receives the wrong quantity of tablets, errors where the patient receives the wrong strength of medication, and errors where two separate patients' prescriptions are packaged together in the same bag. These errors were not recorded as part of any continuous quality improvement program. Brent told the Board's compliance officer that the pharmacy has not "encouraged or discouraged the internal reporting of errors." Since the 2014 complaint, the pharmacy has implemented a functioning CQI program and is reporting errors. (Exh. 5, p. 27, Exh. 8, p. 36, Exh. 9, p. 40; Funk testimony).

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[2] The pharmacy's policy that was in place prior to the 2014 misfill provided, "The pharmacist only shall perform the final verification of the completed order by comparing the NDC of the stock bottle to the NDC on the receipt of each prescription, or by visually inspecting the contents of the dispensing container." (Exh. A).

*2009 Dispensing Error and Subsequent Malpractice Settlement*

In the complaint, H.P.'s mother also referenced a previous misfill that she had heard occurred several years ago. Board compliance officer Andrew Funk investigated this matter. Funk discovered that in 2009, Dwayne dispensed zolpidem, a non-benzodiazeprine sedative/hypnotic indicated for the short-term management of insomnia, to a patient rather than tramadol, a non-narcotic prescription medication indicated for the treatment of moderate to moderate-severe pain, which was actually prescribed.[3] Dwayne gave a statement to his insurance company at the time of the error. Dwayne's insurance company ultimately settled the matter and paid the patient who was subject to the error $86,117.60. The settlement agreement was not reported to the Board. (Exh. 5, pp. 23-24, Exh. 11, p. 45; Funk testimony).

Both Brent and Dwayne were aware of the 2009 misfill when it occurred. Respondents were not aware that a settlement had occurred, however, until the 2014 complaint investigation when they were informed of the settlement by the Board's compliance officer. (Funk, B. Plender testimony).

In response to an inquiry by the pharmacy, Cincinnati Insurance Companies sent a letter to Dwayne dated December 17, 2014. The letter provides:

> This letter is to confirm that Cincinnati Insurance Companies did provide coverage for and settle claim 115283. Incorrect medication (Zolpidem vs Tramadol) was dispensed in the claim.
>
> This claim was settled . . . on January 14, 2011. The total amount of the settlement was $85,000. I did not inform you of this settlement at any time. I was unaware you needed to provide notice to any state agency. Cincinnati Insurance did report the settlement to the State of Iowa.

(Exh. D).

*Patient Counseling*

During the complaint process, H.P.'s mother also alleged that she had not been counseled by Dwayne when she picked up the prescription for H.P. on March 17, 2014. The pharmacy's policy is to counsel patients on all new prescriptions and, if needed, to counsel on refills. The pharmacy uses an electronic signature capture device to record counseling. A patient may refuse counseling by checking a box indicating that consultation has been refused. (B. Plender testimony; Exh. C).

H.P.'s mother picked up and signed for the prescription in question on March 17, 2014. The pharmacy's electronic records reflect that consultation occurred when she picked up

[3] The pharmacy did not implement any substantive changes in the way it processed and verified prescriptions as a result of the 2009 misfill. (B. Plender testimony).

the prescription. Dwayne recalls counseling H.P.'s mother when she picked up the prescription. (Exh. B).

## CONCLUSIONS OF LAW

*Failure to Maintain a CQI Program (Count I: Dutch Mill Pharmacy)/Violating Duties of Pharmacist-in-Charge (Count I: Brent Plender)*

The Board's regulations provide that the pharmacy and the pharmacist in charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.[4] All licensed pharmacies in Iowa are required to implement or participate in a continuous quality improvement (CQI) program.[5] The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of 657 Iowa Administrative Code 8.26.[6]

> 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 the quality of patient care.[7]

A pharmacy is required to develop, implement, and adhere to written policies and procedures for operation and management of the CQI program. The policies and procedures must address a process to identify and document reportable program events. A reportable program event is a preventable medication error that results in the incorrect dispensing of a prescribed drug, including an incorrect drug dispensed, incorrect labeling, or a drug received by the wrong patient.[8] CQI program records must be maintained on site at the pharmacy or be accessible to the pharmacy and be available to the Board for at least two years from the date of the record.[9]

The preponderance of the evidence demonstrates in this case that Respondent Brent Plender and Respondent Dutch Mill Pharmacy violated 657 Iowa Administrative Code 6.2 and 8.26 by failing to have a CQI program compliant with the Board's requirements. Brent acknowledged during the investigation and at hearing that there had been events which are classified as reportable program events under the Board's regulations that were not recorded as part of the pharmacy's CQI program. At the time the Board initiated its investigation of the 2014 complaint, the pharmacy, Brent, and Dwayne were aware of the misfill regarding H.P., yet no written incident report had been made. Brent acknowledged that the pharmacy neither encouraged nor discouraged pharmacists and other staff members from reporting errors prior to the 2014 complaint.

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[4] 657 Iowa Administrative Code (IAC) 8.3(1). All citations to the Iowa Administrative Code in this decision refer to the regulations in effect as of the date of the particular violation alleged.
[5] 657 IAC 8.26.
[6] 657 IAC 8.26(2).
[7] 657 IAC 8.26.
[8] 657 IAC 8.26(1), (3).
[9] 657 IAC 8.26(5).

*Failure to Accurately Verify Prescription (Count II: Dutch Mill Pharmacy; Count I: Dwayne Plender)*

Pursuant to the Board's regulations, the pharmacist must provide and document the final verification for accuracy, validity, completeness, and appropriateness of a patient's prescription or medication order prior to the delivery of the medication to the patient or to the patient's representative.[10] The pharmacy and pharmacist-in-charge share responsibility for making sure that procedures are in place to ensure such verification is occurring.[11]

The preponderance of the evidence demonstrates in this case that Respondent Dwayne Plender violated 657 Iowa Administrative Code 8.3(3) by failing to verify the accuracy of H.P.'s prescription prior to it leaving the pharmacy. Under the pharmacy's visual verification system, Dwayne should have compared the NDC on the stock bottle to the NDC on the prescription to verify that the two matched. Dwayne erred in filling H.P.'s prescription for 5 milligram tablets with 25 milligram tablets from an accurately labeled stock bottle. Dwayne acknowledged that there is a visual difference between the 5 milligram and 25 milligram tablets that he should have recognized upon inspection. There were two opportunities, then, for Dwayne to have caught this error during the verification process. The prescription was not accurately verified.

While the evidence establishes that Dwayne's conduct violated the Board's verification regulations, there is insufficient evidence to establish such a violation for the pharmacy itself. The pharmacy had a visual verification system that, if correctly followed by the pharmacist, would have permitted this error to be caught before the misfilled prescription left the pharmacy. The danger with a visual verification system is that it is more susceptible to human error than an electronic scan verification system, which Dutch Mill Pharmacy switched to after the 2014 complaint. Nevertheless, it was the pharmacist's carelessness, rather than the pharmacy's verification system, that caused the error in this case.

*Failure to Notify Board of Malpractice Settlement (CountIV: Dutch Mill Pharmacy; Count III: Dwayne Plender)*

Under the Board's regulations, disciplinary sanctions may be imposed against any licensee that fails to notify the Board within 30 days after the occurrence of any judgment or settlement of a malpractice court claim or action.[12] It is undisputed here that a malpractice settlement was entered into regarding the 2009 misfill committed by Dwayne. The insurance provider who settled the claim in 2011, however, failed to inform Dwayne or the pharmacy of the settlement. It was not until the 2014

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[10] 657 IAC 8.3(3). This portion of the regulations has subsequently been amended, but this version was in place at the time of the alleged violation.
[11] 657 IAC 8.3(1). This portion of the regulations has subsequently been amended, but this version was in place at the time of the alleged violation.
[12] 657 IAC 36.1(4)(p).

investigation that Dwayne or the pharmacy became aware of the settlement. Under these circumstances, no violation has been proven.

*Failure to Counsel Patient on Change in Dosage (Count III: Dutch Mill Pharmacy; Count II: Dwayne Plender)*

Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy, including but not limited to a change of dose, directions, or drug formulation, a pharmacist is required to counsel each patient or patient's caregiver.[13] A pharmacist is not required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A refusal of consultation must be documented by the pharmacist. In the absence of a documented record of refusal, the presumption is that the offer to counsel was accepted and counseling was provided.[14] The pharmacy shares responsibility for ensuring that pharmacists are providing counseling in accordance with the Board's regulations.[15]

The credible evidence does not support the conclusion that Respondent Dwayne Plender or Respondent Dutch Mill Pharmacy committed the violation alleged. The pharmacy's electronic documentation reflects that H.P.'s mother received counseling on March 17, 2014 when she picked up H.P.'s prescription. In conjunction with the pharmacy's electronic record, the Board found credible Dwayne's testimony regarding having provided counseling.

*Sanction*

The Board may consider a number of factors in determining the nature and severity of the disciplinary sanction to be imposed when a violation is established, including the relative seriousness of the violation as it relates to assuring a high standard of professional care; the facts of the violation; any extenuating circumstances; whether remedial action has been taken; and any other factors that reflect upon the competency, ethical standards, and professional conduct of the licensee.[16]

Respondents argue that the Board has not imposed discipline in the past against other licensees when the violation relates to the lack of a functioning CQI program and a single error. While the Board recognizes that misfills will inevitably accompany pharmacy practice no matter how rigorous the verification process is, a misfill that results in patient harm is particularly troubling to the Board when a pharmacy does not have a functioning CQI program. The purpose of the CQI program is to help the pharmacy to identify errors so that its processes can be corrected and future errors prevented. Without a functioning CQI program, the danger is that a pharmacy will continue to make the same errors repeatedly. In this case, the misfilled prescription was

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[13] 657 IAC 6.14(1).
[14] 657 IAC 6.14(6).
[15] 657 IAC 8.3(1). This portion of the regulations has subsequently been amended, but this version was in place at the time of the alleged violation.
[16] 657 IAC 36.1(3).

for a medically fragile child and resulted in moderate illness and the child missing school. The Board has been consistent in its imposition of discipline where a dispensing error results in patient harm and the pharmacy does not have a compliant CQI program.

The Board recognizes, however, that the pharmacy and pharmacist in charge here have taken steps to improve accuracy in the pharmacy, including implementation of a scan verification system and implementation of a functioning CQI program that includes documentation of reportable events.

With regard to Dwayne Plender, the Board notes that errors that result in misfilled prescriptions are an inevitable part of pharmacy practice. This was an isolated incident and, once notified of the misfill, Dwayne took prompt remedial steps. Under these circumstances, the Board concludes that, although a technical violation of the Board's regulations occurred, no sanction with regard to Respondent Dwayne Plender is warranted.

## DECISION AND ORDER

IT IS THEREFORE ORDERED that Citations and Warnings shall be issued to Respondents Dutch Mill Pharmacy and Brent Plender. Respondents are hereby CITED for the violations established by this record and are WARNED that future violations will result in greater discipline of their licenses.

IT IS FURTHER ORDERED that Respondents Dutch Mill Pharmacy and Brent Plender shall ***each*** pay a civil penalty in the amount of $500. The civil penalty payments shall be made by check, payable to the Treasurer of Iowa, and mailed to the executive director of the Board within 30 days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

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

Dated this 24th day of June, 2015

Edward Maier
Chairperson, Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General

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