BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	Case No. 2014-45
Pharmacist License of	)	
BRENT PLENDER	)	**STATEMENT OF CHARGES**
License No. 17651,	)	**& 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 17651. 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
VIOLATING THE DUTIES OF A PHARMACIST-IN-CHARGE

Respondent is charged with violating the duties of a pharmacist-in-charge in violation of Iowa Code sections 147.55(9) and 155A.12(1) and 657 Iowa Administrative Code rules 6.2, 8.3(1), 8.26(3), and 36.1(4)(*u*).

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 the pharmacist-in-charge 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. The prescription was filled by staff pharmacist, Dwayne Plender. 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 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 a staff pharmacist at Dutch Mill misfilled 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. The pharmacist'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	( ) first class mail
(X) certified mail, return receipt requested	( ) facsimile
Article Number 9171999991703106757 81	( ) 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

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.