BEFORE THE IOWA BOARD OF PHARMACY

Re: Controlled Substance Registration of: **MATTHEW BIGGERSTAFF** Registration Number 1306092 Respondent	)))))	Case No. 2013-195 **ORDER TO SHOW CAUSE**

TO: Matthew Biggerstaff, DO
9468 NE 27th St.
Ankeny, Iowa 50021

NOTICE: Pursuant to the provisions of Iowa Code chapter 124.304–305 (2013) and 657 Iowa Administrative Code rule 10.12(5)–(8), you are hereby ordered to appear before the Iowa Board of Pharmacy to show cause why controlled substance registration number 1306092 issued to Matthew Biggerstaff, DO, should not be suspended or revoked. TO REQUEST A HEARING REGARDING THE SUSPENSION OR REVOCATION OF THIS CONTROLLED SUBSTANCE REGISTRATION, YOU MUST FILE A REQUEST FOR A HEARING BEFORE THE BOARD WITHIN THIRTY (30) DAYS OF ISSUANCE OF THIS ORDER.

I. JURISDICTION

Pursuant to Iowa Code chapter 124 (2013) and 657 Iowa Administrative Code rule § 10.12(5)–(8), the Iowa Board of Pharmacy (Board) has jurisdiction over those who manufacture, distribute, and dispense controlled substances in Iowa. The Board issued Matthew Biggerstaff, DO (Respondent) controlled substance registration number 1306092 subject to the laws of the State of Iowa and the rules of the Board.

II. BASIS FOR ORDER TO SHOW CAUSE

1. Respondent holds a license to practice medicine in the State of Iowa.

2. Respondent's authority for prescribing, possessing, administering, and dispensing controlled substances pursuant to Iowa Code chapter 124 is dependent on his continued adherence to the laws and rules governing controlled substances.

3. Iowa Code section 124.304(*d*) and Iowa Administrative Code rule 657—10.12(1)(*d*) gives the Board authority to suspend or revoke any registration upon finding that the registrant committed acts that would render his registration under Iowa Code section 124.303 inconsistent with the public interest.

4. Iowa Code section 124.303(1) outlines the factors for the Board to consider when determining the public interest. Amongst those factors is compliance with applicable state or local laws.

5. Dr. Biggerstaff gave his password information for Allscripts (electronic prescriptions) program for his office nurse to use.

6. Dr. Biggerstaff gave his Prescription Monitoring Program information to his office nurse to use. PMP records were accessed fives times by the office from 1/1/2009 to 2/2014.

III. ORDER

Respondent is hereby ordered to appear before the Board and show cause why controlled substance registration number 1306092 should not be suspended or revoked.

Respondent may request a hearing before the Board in response to this Order by filing that request within thirty (30) days of the date of this Order. Respondent's request for a hearing should be directed to Lloyd Jessen, Executive Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The Board office telephone number is (515) 281-5944. If Respondent requests a hearing, the hearing will be held at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa, on the date of the next regularly scheduled meeting of the Board.

IF RESPONDENT DOES NOT REQUEST A HEARING IN THIS MATTER

WITHIN THIRTY DAYS OF THE DAYE OF THIS ORDER, RESPONDENT'S CONTROLLED SUBSTANCES REGISTRATION WILL BE SUSPENDED.

IT IS SO ORDERED THIS 26th day of August 2014.

JAMES MILLER, Vice Chairperson
Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Iowa Attorney General
Drug Enforcement Administration, Des Moines, Iowa
Mike Sellers, Attorney for Respondent

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 9171999991703239255424
(X) first class mail
( ) facsimile
( ) other _____

on the 28th day of August, 2014.

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

Annie S Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

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

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

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

Motion in Limine

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

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

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

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

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

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

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

(Emphasis added).

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

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

THE RECORD

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

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[1] Iowa Code § 17A.14(1) (2013).

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

FINDINGS OF FACT

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

Electronic prescriptions

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

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

(Exh. 6).

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

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

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

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

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

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

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

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

> Recently, the Des Moines Resident Office conducted an investigation of your Drug Enforcement Administration (DEA) Registration, which revealed the following violation of Title 21 of the Code of Federal Regulations (CFR):
>
> - 21 CFR 1311.102(a) – The practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person.
>
> This letter is formal notification that your failure to comply with the above regulation constitutes a violation of the Controlled Substances Act, which was outlined by Diversion Investigator George Taylor on April 4, 2014. At this time, you are being afforded the opportunity to voluntarily comply with the requirements of the Controlled Substances Act.

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

(Exh. 15).

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

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

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

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

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

Prescription Monitoring Program (PMP)

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

CONCLUSIONS OF LAW

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

> a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.
> b. Compliance with applicable state and local law.
> c. Any convictions of the applicant under any federal and state laws relating to any controlled substance.
> d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion.
> e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.
> f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.
> g. Any other factors relevant to and consistent with the public health and safety.[6]

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

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

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[3] Iowa Code § 124.302(1) (2013).
[4] 657 Iowa Administrative Code (IAC) 10.1.
[5] Iowa Code § 124.304(1)(d) (2013).
[6] Iowa Code § 124.303(1)(a)-(g) (2013); 657 IAC 10.12(1)(d), 10.12(4) (2013).
[7] Iowa Code § 124.305 (2013).

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

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

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

. . .

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

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

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

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

. . .

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

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657 – 10.21 Prescription requirements

10.21(1) *Form of prescription* . . . If the prescriber utilizes an electronic prescription application that meets DEA requirements for electronic prescriptions, the prescriber may electronically prepare and transit a prescription for a controlled substance to a pharmacy that utilizes a pharmacy prescription application that meets DEA requirements for electronic prescriptions. A prescriber's agent may prepare a prescription for the review, authorization, and manual or electronic signature of the prescriber but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription. An electronic prescription

for a controlled substance shall not be transmitted to a pharmacy except by the prescriber in compliance with DEA regulations. A prescriber shall securely maintain the unique authentication credentials issued to the prescriber for utilization of the electronic prescription application and authentication of the prescriber's electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other prescriber, agent, or individual.

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657 – 21.2 System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders. Authentication credentials shall be securely maintained by the individual to whom the credentials are issued and shall not be shared with or disclosed to any other individual.

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657 – 37.4 Access to database information.

37.4(1) *Prescribers and pharmacists.* A health care practitioner authorized to prescribe or dispense controlled substances may obtain PMP information regarding the practitioner's patient, or a patient seeking treatment from the practitioner, for the purpose of providing patient health care.
a. Prior to being granted access to PMP information, a practitioner shall submit a request for registration and program access . . . The PMP administrator shall take reasonable steps to verify the identity of a practitioner and to verify a practitioner's credentials prior to providing a practitioner with a secure login and initial password. Except in an emergency when the patient would be placed in greater jeopardy by restricting PMP information access to the practitioner, a registered practitioner shall not share the practitioner's secure login and password information and shall not delegate PMP information access to another health care practitioner or to the practitioner's agent.[8]

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

21 C.F.R. 1311.102 Practitioner responsibilities.

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

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

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

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

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

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

ORDER

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

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

Dated this 6 day of January, 2014

Edward Maier
Chairperson, Iowa Board of Pharmacy

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

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