

**BEFORE THE IOWA BOARD OF PHARMACY**

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Re:	)	Case No. 2013-60
Nonresident Pharmacy License of	)	
<b>CYSTIC FIBROSIS SERVICES,</b>	)	<b>STATEMENT OF CHARGES</b>
<b>INC. PHARMACY</b>	)	<b>&amp; NOTICE OF HEARING</b>
License No.3013,	)	
Respondent.	)	

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**COMES NOW** the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3). Respondent was issued Iowa nonresident pharmacy license number 3013. Respondent's nonresident pharmacy license is active and will expire on December 31, 2013.

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

Hearing. A disciplinary contested case hearing shall be held on August 27, 2013, before the Iowa Board of Pharmacy. The hearing shall be held during the afternoon hearing session, beginning at 1:00 p.m. and shall be located in the Board conference room located at 400 S.W. 8<sup>th</sup> 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 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  
2<sup>nd</sup> Floor Hoover State Office Building  
Des Moines, Iowa 50319.

Ms. Gavin may also be reached by phone at (515)281-6736 or by 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 Assistant Attorney General Meghan Gavin at (515) 281-6736 or at Meghan.Gavin@iowa.gov.

## **B. LEGAL AUTHORITY AND JURISDICTION**

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2011).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 148C, and 272C (2011) and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

## **C. CHARGES**

### **COUNT I VIOLATING LAWS OF ANOTHER STATE**

Respondent is charged pursuant to Iowa Code § 155A.15(2)(c) (2013), and 657 Iowa Administrative Code §§ 36.1(4)(j) and 36.1(4)(ad), with violating the laws of another state which relate to the practice of pharmacy.

## **D. FACTUAL CIRCUMSTANCES**

1. Respondent is a licensed nonresident pharmacy in the State of Iowa. Respondent's nonresident pharmacy license is active and will expire on December 31, 2013.
2. On February 15, 2013, Respondent self-reported disciplinary action against its

Colorado registration as an in-state prescription drug outlet.

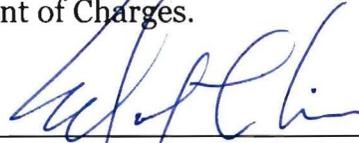
3. On April 25, 2012, the Colorado Board of Pharmacy and Respondent entered into a Stipulation and Final Agency Order due to Respondent procuring a product determined under Colorado law to be a prescription drug, from a source that is not registered by the Board to distribute prescriptions drugs into Colorado.
4. The parties agreed in this Stipulation and Final Agency Order that Respondent would procure prescription drugs only from sources registered with the Board, and would pay a \$5,000 fine with a \$500 surcharge.

#### **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 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Theresa Weeg.

#### **F. PROBABLE CAUSE FINDING**

On this 26<sup>th</sup> day of June, 2013, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



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EDWARD L. 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:

- |  |   |
|--|---|
| <input type="checkbox"/> personal service                                    | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile        |
| Article Number 91771999991703104136582                                       | <input type="checkbox"/> other _____      |

on the 27<sup>th</sup> day of June, 2013.

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

  
Debbie S. Jorgenson

BEFORE THE BOARD OF PHARMACY

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Re:	)	DIA NO: 130PHB042
	)	CASE NO: 2013-60
Nonresident Pharmacy License of	)	
<b>Cystic Fibrosis Services, Inc.</b>	)	
<b>Pharmacy,</b>	)	
	)	
License No. 3013,	)	<b>FINDINGS of FACT,</b>
	)	<b>CONCLUSIONS of LAW,</b>
Respondent.	)	<b>and ORDER</b>

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On June 26, 2013, the Iowa Board of Pharmacy (the Board) filed a statement of charges against Cystic Fibrosis Services, Inc. Pharmacy (respondent). The Board charged respondent with violating another state's laws relating to pharmacy. The case was set for hearing on November 5, 2013. A quorum of the Board was present. Jeffrey Farrell, an administrative law judge from the Iowa Department of Inspections and Appeals, assisted the Board. Assistant Attorney General Meghan Gavin represented the public interest. Attorney Kevin Reynolds represented respondent.

**THE RECORD**

The state's exhibits 1-5 were admitted into the record. Respondent's exhibits A-B were also admitted.

**FINDINGS OF FACT**

Respondent is a licensed pharmacy with a headquarters in Centennial, Colorado. Respondent also has a nonresident pharmacy license in Iowa. On March 28, 2013, the Board received a self-report from respondent that it had entered into a stipulation and order to resolve a charge by the Colorado Pharmacy Board (Colorado Board). The Colorado Board alleged that respondent procured a product deemed to be a prescription drug from a source that was not registered by the Colorado Board. Respondent agreed to pay a \$5,000.00 fine and a ten percent surcharge for the violation. (Exhibit 4).

Respondent stated that the dispute with Colorado concerned a good faith legal interpretation. It considered the product, hypertonic saline, to be a "device" that was not subject to regulation by the Colorado Board. Respondent purchased the product from a legitimate wholesaler, so the only issue concerned whether the product was subject to regulation by the Colorado Board. (Exhibits 4, A-B).

Respondent argued that Iowa should not impose a sanction for out of state discipline because it would equate to a double penalty. Respondent also expressed the concern that it would have to report any action taken by the Board, which would give the appearance of being disciplined for a separate substantive offense. Respondent asked the Board to impose no discipline at all. In the alternative, respondent argued that a letter of education would be sufficient. Respondent asked that the letter expressly state that respondent need not report the Board's action as discipline.

### CONCLUSIONS OF LAW

The Board was created for the express purpose to promote, preserve and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy.<sup>1</sup> The Board regulates the practice, in part, through the licensing of pharmacies, pharmacists, and others engaged in the sale, deliver, or distribution of prescription drugs and devices. The Board has the authority to grant licenses, adopt regulatory standards for licensure, and to enforce compliance with those standards.<sup>2</sup> The Board may impose discipline against the license holder, including revoking or suspending a license, putting a licensee on probation, imposing a civil penalty up to \$25,000, issuing a citation and warning, and requiring professional education.<sup>3</sup>

In this case, the Board charged respondent with violating a law relating to the practice of pharmacy in another state.<sup>4</sup> The documentation unquestionably demonstrates that the Colorado Board disciplined respondent for a violation of Colorado's laws relating to the purchase of a prescription drug from a source that was not registered to distribute. Respondent may have had a good faith belief that it was acting in accordance with the law, but it ultimate accepted a settlement imposing a \$5,000.00 fine. Respondent further agreed to comply with the Colorado Board's interpretation of its regulations. The Board's statement of charges is supported by the record.

### SANCTION

The Board is mindful of the argument made by respondent. There is a risk of unnecessarily multiplying penalties in cases involving out-of-state discipline. If the other state imposed a suspension or probation, the evaluation could be different because the Board has an interest in entering the same sanction to track the licensee compliance with terms of any probation or suspension. However, when the primary sanction is a fine, the purpose for level of fine imposed by the original jurisdiction might be undermined if

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<sup>1</sup> Iowa Code section 155A.2.

<sup>2</sup> Iowa Code section 272C.1(6)(q), 272C.3.

<sup>3</sup> Iowa Code sections 155A.12, 155A.18, 272C.3(2).

<sup>4</sup> 657 IAC 36.1(4)(j), 36.1(4)(ad).

other states imposed additional fines. Any such determination will be dependent on the circumstances involved and needs to be considered on a case by case basis.

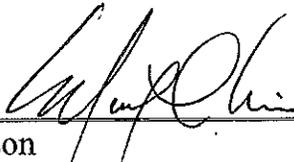
The Board's concern here is that respondent did not immediately inform Iowa about the action taken in Colorado. The Board has a rule requiring licensees to notify the Board within 30 days after a decision has been made by another jurisdiction. 657 IAC 36.1(4)(k). The statement of charges did not independently allege a violation of this regulation, but it is reasonable to consider the regulation when considering the level of sanction. Respondent inferred that any sanction should be mitigated because it was self-reported; if so, the timing of any self-report may be considered as well.

The Colorado Board entered its final agency order on April 20, 2012. Respondent did not file information regarding the Colorado order with the Board in Iowa until March 28, 2013, nearly a year later. Under these circumstances, the Board finds some level of sanction is warranted. The Board believes it can impose a penalty that will not infringe on the level of sanction intended by the Colorado Board.

### **DECISION AND ORDER**

The Iowa Board of Pharmacy finds that respondent Cystic Fibrosis Services, Inc. Pharmacy committed a violation of the regulations cited in the statement of charges. The Board imposes a citation and warning, and \$500.00 civil penalty based on the violation. Respondent shall also pay \$75.00 for fees associated with conducting the disciplinary hearing. Respondent shall remit payment of the civil penalty and the hearing fees to the Board at the following address: Iowa Board of Pharmacy Examiners, 400 SW 8<sup>th</sup> St., Suite E, Des Moines, Iowa 50309-4688. In addition, the executive secretary of the board may bill respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondent shall remit for these expenses within thirty days of receipt of the bill.

Dated this 14<sup>th</sup> day of January 20 14.



Chairperson  
Iowa Board of Pharmacy Examiners

cc: Meghan Gavin, Assistant Attorney General  
Kevin Reynolds, Respondent Attorney

**Notice**

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.

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