

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|----------------------------------|---|--------------------------------|
| Re: |) | Case No. 2013-9 |
| Nonresident Pharmacy Licenses of |) | |
| AMERIDOSE LLC |) | STATEMENT OF CHARGES |
| License Nos. 3828 and 3829, |) | & NOTICE OF HEARING |
| and Wholesale Drug Licenses of |) | |
| AMERIDOSE LLC |) | |
| License Nos. 6859 and 6569, |) | |
| 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). Respondent was issued Iowa nonresident pharmacy license numbers 3828 and 3829 and Iowa wholesale drug licenses 6859 and 6569. Respondent's licenses were active until December 31, 2012.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on April 23, 2013, before the Iowa Board of Pharmacy. 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 Assistant Attorney General Meghan Gavin at (515)281-6736.

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

FAILURE TO COMPLY WITH LAWS AND RULES OF THE HOME STATE

Respondent is charged with repeated failing to comply with the pharmacy laws and rules of its home state of Massachusetts in violation of Iowa Code sections 155A.13A(1)(b) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 19.10 and 36.(4)(ad).

Count II

FAILURE TO COMPLY WITH IOWA PHARMACY RULES AND COMPOUNDING REQUIREMENTS

Respondent is charged with failing to comply with Iowa pharmacy rules and compounding requirements in violation of Iowa Code sections 155A.13A(1)(b) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 19.3, 20.1, 20.3, 20.10, 20.12, and 36.1(4)(j).

Count III
**HAVING A LICENSE TO PRACTICE PHARMACY ISSUED BY ANOTHER STATE
CANCELED, REVOKED, OR SUSPENDED**

Respondent is charged with having its license to practice pharmacy issued by another state canceled, revoked, or suspended for conduct substantially equivalent to any grounds for disciplinary action in Iowa in violation of Iowa Code sections 155A.13A(1)(b) and 155A.15(2)(c) and 657 Iowa Administrative Code rules 19.3 and 36.4(ae).

D. FACTUAL CIRCUMSTANCES

1. Respondent holds Iowa nonresident pharmacy license numbers 3828 and 3829 and Iowa wholesale drug license numbers 6859 and 6569. At all times material to the charges, Respondent operated a nonresident pharmacy and a wholesale drug business at 201 Flanders Rd., Westborough, Massachusetts 01581 (3828) and a nonresident pharmacy and a wholesale drug business at 205 Flanders Rd., Westborough, Massachusetts 01581 (3829). Sophia Pasedis is the pharmacist in charge of nonresident pharmacy license number 3828 and the vice president of regulatory affairs for wholesale license number 6569. Bryan O'Neill is the pharmacist in charge of nonresident pharmacy license number 3829 and the manager in charge of wholesale license number 6859.

2. On September 24, 2012, the Massachusetts Department of Public Health (MDPH) was notified by the Tennessee Department of Health about a cluster of six rare fungal meningitis cases.

3. The patients had each received an epidural injection of steroid compounded at New England Compounding Center.

4 MDPH initiated an investigation of New England Compounding Center on September 25.

5. On October 3, the Massachusetts Board of Pharmacy accepted New England Compounding Center's voluntary surrender of its pharmacy license.

6. Based on the shared ownership and leadership with New England Compounding Center, MDPH requested that Respondent cease all pharmacy operations and any dispensing, manufacturing, or wholesale distribution of any products starting at October 10, 2012. The Respondent agreed. This agreement has been extended on several occasions. As of the filing of this Statement of Charges, the Respondent has agreed to cease all pharmacy operations and distribution of products until February 22, 2013.

7. MDPH and the Federal Drug Administration began an on-site investigation of the Respondent. The investigation is ongoing.

8. The investigation of the Respondent's sister company, New England Compounding Center (NECC), concluded that NECC violated numerous laws and regulations related to the practice of pharmacy. The outbreak of fungal meningitis attributable to NECC has affected 693 people in at least 19 states and is alleged to have caused the death of 45 patients.

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 30th day of January, 2013, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



SUSAN M. FREY, 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

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|---------------------------------|---|----------------------------------|
| Re: |) | Case No. 2013-9 |
| Nonresident Pharmacy License of |) | |
| AMERIDOSE LLC |) | |
| License Nos. 3828 and 3829 |) | STATE'S MOTION TO DISMISS |
| and Wholesale Drug Licenses of |) | |
| AMERIDOSE LLC |) | |
| License Nos. 6859 and 6569 |) | |
| Respondent. |) | |

COMES NOW the State of Iowa, by and through the undersigned, and moves to dismiss the above-captioned contested case proceeding. In support thereof, the State respectfully states the following:

1. The Iowa Board of Pharmacy filed a Statement of Charges against the Respondent on January 30, 2013.
2. The charges were based on Respondent's connection to the fungal meningitis outbreak in the fall of 2012 and the actions taken by the Massachusetts Board of Pharmacy in response.
3. Respondent closed down in the fall of 2012 and never reopened. Respondent does not have any active licenses with the Massachusetts Board of Pharmacy (See Exhibit A).
4. Respondent's Iowa licenses expired on December 31, 2012.
5. Because Respondent's business has been defunct for some time, the State believes it would be futile to proceed.
6. The public is not at risk because Respondent is not in operation. Should Respondent ever submit an application to the Board, the matters described in the charges could be reviewed at that time.
7. As a result, the State believes that the above-captioned contested case should be dismissed without prejudice.

WHEREFORE the State respectfully requests the Board dismiss the above-captioned contested case proceeding.

Respectfully submitted,

THOMAS J. MILLER
ATTORNEY GENERAL OF IOWA

RECEIVED

FEB 12 2015

IOWA BOARD OF PHARMACY

Laura Steffensmeier

LAURA STEFFENSMEIER
Assistant Attorney General
Hoover Building, 2nd Floor
1305 East Walnut Street
Des Moines, Iowa 50319
(515) 281-6690
laura.steffensmeier@iowa.gov
ATTORNEYS FOR THE STATE

Original Filed.

Copies to:

Ameridose LLC
201 Flanders Rd.
Westborough, MA 01581

Ameridose LLC
205 Flanders Rd.
Westborough, MA 01581

Proof of Service

The undersigned certifies that the foregoing instrument was served upon each of the persons identified as receiving a copy by delivery in the following manner on the 11th day of February, 2015.

| | |
|---|--|
| <input checked="" type="checkbox"/> U.S. Mail | <input type="checkbox"/> FAX |
| <input type="checkbox"/> Hand Delivery | <input type="checkbox"/> Overnight Courier |
| <input type="checkbox"/> Federal Express | <input type="checkbox"/> Other |
| <input type="checkbox"/> Electronically | |

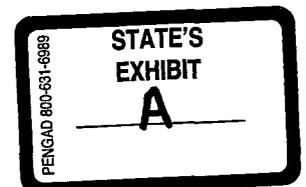
Signature: *R. Daley*

Search Results

- Select the licensee name below for more information. (If your search produced more than one page, you may select page numbers at the bottom of this screen.)
- Select the **Search for a Person** or **Search for a Facility** button to perform a new search.
- Select the **Preview File** button to view a sample of the fields included in a file you can download.
- Select the **Download File** button to download a text file of your search results at no charge.
- Select [Public Information Request Form](#) for a form to order a data file.

| <u>Name</u> | <u>License Number</u> | <u>License Type</u> | <u>License Status</u> | <u>Expiration Date</u> | <u>Address</u> |
|--------------------------------|-----------------------|---|--|---------------------------|--------------------------|
| Ameridose, LLC | CF3467 | Certificate of Fitness | Business Relocation | 12/31/2011 12:00:00 AM | Framingham MA 01702 |
| Ameridose, LLC | DS3467 | Retail Drug Store Permit | Business Relocation | 12/31/2011 12:00:00 AM | Framingham MA 01702 |
| Ameridose, LLC | CS3467 | Controlled Substance Permit | Business Relocation | 12/31/2011 12:00:00 AM | Framingham MA 01702 |
| Ameridose, LLC | DS89641 | Retail Drug Store Permit | Expired - Restriction by Agreement Order | 12/31/2013 12:00:00 AM | Westborough, MA 01581 |
| Ameridose, LLC | CS89641 | Controlled Substance Permit | Expired - Restriction by Agreement Order | 12/31/2013 12:00:00 AM | Westborough MA 01581 |
| Ameridose, LLC | CF89641 | Certificate of Fitness | Expired - Restriction by Agreement Order | 12/31/2013 12:00:00 AM | Westborough MA 01581 |
| Ameridose, LLC | CS89750 | Controlled Substance Permit | Expired - Restriction by Agreement Order | 12/31/2013 12:00:00 AM | Westborough MA 01581 |
| Ameridose, LLC | DS89750 | Retail Drug Store Permit | Expired - Restriction by Agreement Order | 12/31/2013 12:00:00 AM | Westborough MA 01581 |
| Ameridose, LLC | CF89750 | Certificate of Fitness | Expired - Restriction by Agreement Order | 12/31/2013 12:00:00 AM | Westborough MA 01581 |
| Ameridose, LLC | WD501 | Wholesale Distributor Permit | Expired - Restriction by Agreement Order | 11/30/2013 12:00:00 AM | Westborough MA 01581 |
| Ameridose, LLC | WD501CS | Wholesale Distrib. Controlled Substance | Expired - Restriction by Agreement Order | 11/30/2013 12:00:00 AM | Westborough MA 01581 |

1



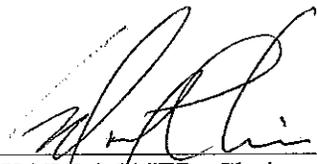
BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|---------------------------------|---|-----------------|
| Re: |) | Case No. 2013-9 |
| Nonresident Pharmacy License of |) | |
| AMERIDOSE LLC |) | |
| License Nos. 3828 and 3829 |) | ORDER |
| and Wholesale Drug Licenses of |) | |
| AMERIDOSE LLC |) | |
| License Nos. 6859 and 6569 |) | |
| Respondent. |) | |

On March 10, 2015, the State's Motion to Dismiss the above-captioned contested case proceeding against Ameridose LLC came before the Board for consideration. After consideration, the Board voted to grant the motion for the reasons stated in the motion.

IT IS THEREFORE ORDERED that the State's Motion to Dismiss is granted.

Dated this 10th day of March, 2015.



EDWARD MAIER, Chairperson
IOWA BOARD OF PHARMACY