

## WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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The status of an appeal may be found on court access websites at:

<http://ccap.courts.state.wi.us/InternetCourtAccess> and <http://www.courts.state.wi.us/wscca>

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STATE OF WISCONSIN  
BEFORE THE PHARMACY EXAMINING BOARD

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IN THE MATTER OF DISCIPLINARY :  
PROCEEDINGS AGAINST :  
: FINAL DECISION AND ORDER  
AMEX PHARMACY, :  
RESPONDENT. : **0004940**

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Division of Legal Services and Compliance Case No. 16 PHM 070

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

AmEx Pharmacy  
1515 Elizabeth St., Ste. J  
Melbourne, FL 32901

Wisconsin Pharmacy Examining Board  
P.O. Box 8366  
Madison, WI 53708-8366

Division of Legal Services and Compliance  
Department of Safety and Professional Services  
P.O. Box 7190  
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Respondent AmEx Pharmacy is licensed in the state of Wisconsin as an out-of-state pharmacy, having license number 593-43, first issued on September 20, 2010 and current through May 31, 2018. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 1515 Elizabeth Street, Suite J, Melbourne, Florida 32901.

2. At all times relevant to this matter, Respondent held and currently holds a Special Sterile Compounding Pharmacy permit, number PH27532, issued by the State of Florida.

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3. Respondent engages in the sterile transfer of volumes of Avastin® (bevacizumab).

4. Avastin® is commonly packaged in 100 mg/4 mg/mL vials. Respondent transfers one vial into approximately 80 1.25 mg/0.05 mL silicone syringes and transfers the volume of approximately 20,000 to 50,000 syringes of Avastin® per month. Respondent distributes the Avastin® syringes to physician's offices in 41 states.

5. On February 29, 2016, the State of Florida Department of Health issued an Emergency Restriction Order (ERO) which immediately prohibited Respondent from performing sterile compounding.

6. The ERO issued to Respondent was based on the following facts:

- a. In or around 2009, Respondent experienced multiple instances of the needles on the silicone syringes being blocked from an unknown substance, resulting in the plunger not advancing.
- b. A November 2009 report indicated that the needles were being blocked by a "silicone material."
- c. Respondent failed to perform any remediation to correct this issue, despite the analytical report indicating the silicone-based syringe was leeching into the Avastin® solution, causing the syringe to malfunction.
- d. Since January 2015, Respondent received 363 consumer complaints about the plunger not advancing. Respondent failed to review and investigate the complaints and failed to have written procedures to correct and prevent the problem from occurring.
- e. Respondent also received a total of 917 consumer complaints related to a cloudy syringe, plunger not advancing, fibers found on the needles of the syringe and under-filling of the packages of Avastin®. These complaints were not reviewed or investigated, nor did Respondent have written procedures to correct and prevent these problems from occurring.
- f. Respondent failed to ensure compounding personnel engaged in proper aseptic techniques while transferring Avastin® from vials to syringes.
- g. Respondent failed to have written procedures for compounding personnel to accurately measure the quantity of Avastin® in each syringe.
- h. Respondent failed to ensure compounding personnel accurately measured the quantity of Avastin® in each syringe.
- i. Respondent failed to require a media-fill test that simulated the most challenging or stressful compounding scenario.

- j. Respondent failed to require each compounding technician undergo a complete media-fill test.
- k. Respondent failed to record the results of each compounding technician's media-fill test.
- l. Respondent failed to require each compounding technician to undergo environmental sampling.
- m. Respondent failed to require each compounding technician to appropriately undergo gloved-fingertip testing.
- n. Respondent failed to immediately cease compounding practices when colony forming unit populations were found in the anteroom.
- o. Respondent failed to ensure sterility of Avastin® prior to distribution.
- p. Respondent was unable to identify patients that received potentially contaminated units of Avastin®.
- q. Respondent distributed batches of Avastin® after lots of those batches were found to be unsterile.
- r. Respondent failed to appropriately address the contamination of Avastin® by silicone leakage.

7. On April 22, 2016, the State of Florida Department of Health inspected Respondent's facilities to assess compliance with professional standards. As a result of the inspection, the State of Florida Department of Health terminated the ERO as no longer necessary.

8. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

#### CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. The February 29, 2016, Emergency Restriction Order issued by the State of Florida Department of Health, constitutes disciplinary action by a licensing authority, i.e., the State of Florida.

3. By the conduct described in the Findings of Fact, Respondent AmEx Pharmacy engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17), by having been subject to other disciplinary action by a licensing authority of another jurisdiction.

4. As a result of the above violations, Respondent AmEx Pharmacy is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

1. The attached Stipulation is accepted.
2. Respondent AmEx Pharmacy is REPRIMANDED.
3. Within ninety (90) days from the date of this Order, AmEx pharmacy shall pay forfeiture in the amount of \$5,000.00.
4. Within ninety (90) days from the date of this Order, AmEx Pharmacy shall pay COSTS of this matter in the amount of \$500.00.
5. Payment of forfeiture and costs (made payable to the Wisconsin Department of Safety and Professional Services) shall be sent by Respondent to the Department Monitor at the address below:

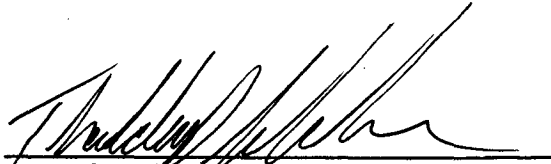
Department Monitor  
Division of Legal Services and Compliance  
Department of Safety and Professional Services  
P.O. Box 7190, Madison, WI 53707-7190  
Telephone (608) 267-3817; Fax (608) 266-2264  
[DSPSMonitoring@wisconsin.gov](mailto:DSPSMonitoring@wisconsin.gov)

6. Violation of any of the terms of this Order may be construed as conduct imperiling public health, safety and welfare and may result in a summary suspension of Respondent's license. The Board in its discretion may in the alternative impose additional conditions and limitations or other additional discipline for a violation of any of the terms of this Order. In the event Respondent fails to timely submit payment of forfeiture and costs as ordered, Respondent's license (no. 593-43) may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with payment of forfeiture and costs.

7. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by:

  
A Member of the Board

9/22/14  
Date

STATE OF WISCONSIN  
BEFORE THE PHARMACY EXAMINING BOARD

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IN THE MATTER OF DISCIPLINARY	:	
PROCEEDINGS AGAINST	:	
	:	STIPULATION
AMEX PHARMACY,	:	0004940
RESPONDENT.	:	

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Division of Legal Services and Compliance Case No. 16 PHM 070

Respondent AmEx Pharmacy and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:


1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.
  2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:
    - the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
    - the right to confront and cross-examine the witnesses against Respondent;
    - the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
    - the right to testify on Respondent's own behalf;
    - the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
    - the right to petition for rehearing; and
    - all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.
  3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation.
  4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.
  5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division
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of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

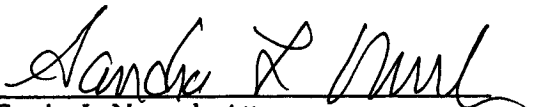
6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

  
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AmEx Pharmacy, Respondent  
C/O Edwin Bayo, Attorney  
1515 Elizabeth St., Ste. J  
Melbourne, FL 32901  
License no. 593-43

08/31/2016  
Date

  
\_\_\_\_\_  
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Division of Legal Services and Compliance  
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8/31/16  
Date