

WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

PHARMEDIUM SERVICES, LLC,
RESPONDENT.

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FINAL DECISION AND ORDER

0004153

Division of Legal Services and Compliance Case No. 13 PHM 010

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

PharMEDium Services, LLC
12620 W. Airport Blvd. Ste. 130
Sugar Land, TX 77478

PharMEDium Services, LLC
913 North Davis Avenue
Cleveland, MS 38732

PharMEDium Services, LLC
6100 Global Drive
Memphis, TN 38141

PharMEDium Services, LLC
43 Distribution Blvd.
Edison, NJ 08817

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 PharMedium Services, LLC, has pharmacies in four locations, each licensed in the state of Wisconsin as an out-of-state pharmacy, having license numbers 315-43, 343-43, 344-43, and 364-43, which are all current through May 31, 2016. Respondent's most recent addresses on file with the Wisconsin Department of Safety and Professional Services (Department) respectively are 126 West Airport Boulevard, Suite 130, Sugarland, Texas 77478;

913 North Davis Avenue, Cleveland, Mississippi 38732; 6100 Global Drive, Memphis, Tennessee 38141; and 43 Distribution Boulevard, Edison, New Jersey 08817.

2. In cooperation with the Division's investigation, on June 18, 2015, Respondent licensed all four out-of-state pharmacies to practice as wholesale distributors of prescription drugs in the state of Wisconsin.

3. Since at least 2012, Respondent has compounded large volumes of prescription drug products for which sterile conditions are required.

4. Respondent sells, without patient-specific prescriptions, the bulk compounded prescription drug products to hospitals and institutional pharmacies located in Wisconsin.

5. Respondent does not administer or dispense the compounded prescription drug products pursuant to a prescription to any individual patient.

6. On November 27, 2013, the Compounding Quality Act was enacted, which added Section 503B to the Food, Drug and Cosmetic Act (FDCA).

7. On December 11, 2013, Respondent, in accordance with Section 503B of the FDCA, registered with the Food and Drug Administration (FDA) as a human drug compounding outsourcing facility. Respondent had maintained a drug manufacturer registration with the FDA prior to registering as an outsourcing facility under Section 503B.

8. Respondent neither admits nor denies the allegations. However, 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. Pursuant to Wis. Stat. § 450.01(8), "distribute" means to deliver, other than by administering or dispensing.

3. Pursuant to Wis. Stat. § 450.01(23), "wholesale distribution" means distribution of a prescription drug to a person other than a consumer or patient.

4. None of the statutory exceptions to the definition of "wholesale distribution" applies to Respondent's conduct in the state of Wisconsin. See Wis. Stat. § 450.01(23)(a-o).

5. Pursuant to Wis. Stat. § 450.01(24), "wholesale distributor" means a person engaged in the wholesale distribution of prescription drugs".

6. Pursuant to Wis. Stat. § 450.071(1), no person may engage in the wholesale distribution of a prescription drug in this state without obtaining a license from

the board for each facility from which the person distributes prescription drugs. The board shall exempt a manufacturer that distributes prescription drugs or devices manufactured by the manufacturer from licensing and other requirements under this section to the extent the license or requirement is not required under federal law or regulation, unless the board determines that it is necessary to apply a requirement to a manufacturer.

7. Respondent's conduct as set out in the Findings of Fact above, constitutes the unlicensed practice as a wholesale distributor in violation of Wis. Stat. § 450.071(1).

8. Pursuant to Wis. Stat. § 450.10(1)(a)2., Respondent's practice as an unlicensed wholesale distributor constitutes unprofessional conduct.

9. By the conduct set out in the Findings of Fact above, Respondent has engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(1) by supplying a drug as prohibited by law.

10. As a result of the above violations, PharMEDium Services, LLC, is subject to discipline pursuant to Wis. Stat. § 450.10(1)(a)2.

ORDER

1. The attached Stipulation is accepted.

2. Respondent PharMedium Services, LLC, is REPRIMANDED.

3. Respondent hereby relinquishes the licenses to practice as an out-of-state pharmacy issued to PharMedium Services, LLC (license numbers 315-43, 343-43, 344-43, and 364-43).

4. Within ninety (90) days from the date of this Order, Respondent shall pay COSTS of this matter in the amount of \$1,102.00.

5. Within ninety (90) days from the date of this Order, Respondent shall pay a FORFEITURE in the amount of \$10,000.00.

6. 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:

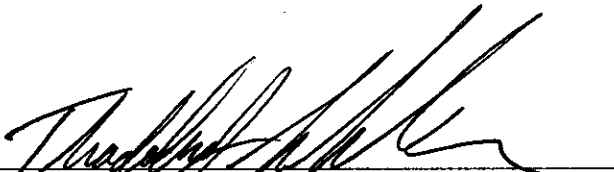
Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

7. 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 or costs as ordered, Respondent's license(s) as a Wholesale Distributor of Prescription Drugs 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.

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

WISCONSIN PHARMACY EXAMINING BOARD

by:


A Member of the Board

7/22/15
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

PHARMEDIUM SERVICES, LLC,
RESPONDENT.

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:

STIPULATION

0004153

Division of Legal Services and Compliance Case No. 13 PHM 010

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

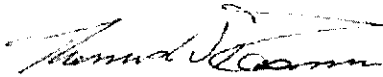
1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.
2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives 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

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.

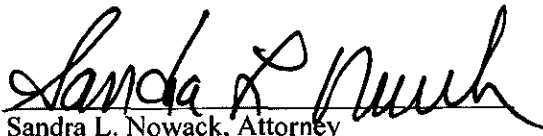
7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

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.



PharMedium Services, LLC, Respondent
Thomas W. Rasnic, Authorized Representative
150 N. Field Dr.
Lake Forest, IL 60045
License nos. 315-43, 343-43, 344-43 and 364-43

7-1-2015
Date



Sandra L. Nowack, Attorney
WI State Bar No. 1025643
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190
Tel. (608) 266-8098
Fax (608) 266-2264
sandra.nowack@wisconsin.gov

7/1/2015
Date