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	:	
	:	FINAL DECISION AND ORDER
MD CUSTOM RX, RESPONDENT.	:	0004041

Division of Legal Services and Compliance
Case Nos. 13 PHM 055, 14 PHM 057 and 14 PHM 075

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

MD Custom RX
19035 W. Capital Dr., Ste. 105
Brookfield, WI 53045

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 MD Custom RX is licensed in the state of Wisconsin to practice pharmacy, having license number 8844-42, first issued on May 30, 2008 and current through May 31, 2016. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 19035 West Capital Drive, Suite 105, Brookfield, Wisconsin 53045.

2. Between approximately May 2011 and December 2013, MD Custom RX produced compounded pharmaceutical products, including controlled substances, without valid prescriptions for individually-identified patients.

Case No. 13PHM055

3. In November 12, 2013, Respondent proactively reported a potential sterility failure at Respondent facility. The report resulted in the recall of a compounded pharmaceutical product.

4. Between December 3, 2013 and December 10, 2013, a Division consumer protection investigator and U.S. Food and Drug Administration (FDA) investigators inspected the facility of MD Custom RX. The investigators observed serious deficiencies in Respondent's practices for producing sterile pharmaceutical products. The investigators' observations were based on current "Good Manufacturing Practices".

5. On December 30, 2013, Respondent voluntarily ceased the practice of preparing sterile pharmaceutical products.

6. On May 21, 2014, Respondent voluntarily ceased the practice of compounding pharmaceutical products without valid prescriptions for individually-identified patients.

7. On July 7, 2014, a Division consumer protection investigator and an FDA drug specialist re-inspected Respondent's facility. The inspection confirmed that Respondent had ceased the practices of sterile compounding and compounding pharmaceutical products for "office use" or without a patient-specific prescription.

Case No. 14 PHM 057

8. On May 14, 2014, MD Custom RX dispensed to Patient A a compounded pharmaceutical product that was supposed to have included diphenhydramine (alcohol base).

9. Patient A discovered that the compounded pharmaceutical product she received from MD Custom RX was actually "diphenhydramine hydrochloride USP ethanol", i.e., *denatured*-ethyl alcohol.

10. The Division notified Respondent of the use of denatured alcohol in Patient A's compounded pharmaceutical product.

11. Respondent acknowledged that the use of the denatured alcohol was a human error and created an unacceptable risk of harm to Patient A.

12. Respondent explained that human error allowed the products with denatured alcohol to be distributed to 64 patients in Wisconsin.

13. Respondent acknowledged responsibility for the error.

14. At the Division's direction, on June 24, 2014, Respondent provided documentation of the following:

a. Detailed attempts at contacting all patients (three minimum attempts required);
b. Documentation of adverse effects for each patient;

c. MD Custom RX's efforts to retrieve all unused portions of recalled preparation at MD Custom RX's expense;
d. That MD Custom RX provided or offered to provide new preparations to patients at MD Custom RX's expense;
e. A detailed sequence of events which lead to the error; and
f. That Department-approved letters were sent to all affected patients and their prescribing physicians discussing the recall and providing them with information as to how to report adverse side effects. The correspondence was to include mention of the FDA's adverse Event Reporting System and the Department website.

Case No. 14 PHM 075

15. Between at least June 14, 2012, and July 7, 2014, MD Custom RX, furnished a prescriber with prescription order blanks imprinted with the name of the pharmacy, "MD Custom RX", in large bold font on the top of the prescription order blank. The prescription order blanks were used for new orders as well as for re-fills.

16. The pre-printed prescription blanks also contained a bold sub-heading "RX Blank for Fox Valley Wellness—Dr. Meress."

17. At the bottom of the pre-printed prescription order blanks, in large bold print, was the instruction, "Fax Form to: MD Custom RX 262-xxx-xxxx" (the fax number for MD Custom RX).

18. Respondent has cooperated fully and responsibly with the Division's requests and investigation.

19. Respondent neither admits nor denies the allegations, and denies deliberate wrongdoing. 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 Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 355(a) and 352(f)1 prohibits compounding, distributing and dispensing pharmaceutical products without valid prescriptions for individually-identified patients.

3. By the conduct set out in the Findings of Fact, MD Custom RX permitted its staff to compound, distribute and dispense pharmaceuticals in violation of the FDCA 21 U.S.C. §§ 355(a) and 352(f)1, respectively, which constitutes unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(1).

4. Under the circumstances of this case, MD Custom RX, by allowing a compounded pharmaceutical product containing denatured alcohol to be distributed to 64 patients, failed to meet the requirements of Wis. Admin. Code § Phar 7.01(1)(d).

5. MD Custom RX's failure to conform employee practice to the requirements of Wis. Admin. Code § Phar 7.01(1)(d) constitutes unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(2).

6. MD Custom RX's conduct in furnishing a prescriber with a prescription order blank imprinted with the name of the specific pharmacy for other than refill orders constituted unprofessional conduct as defined by Wis. Admin. Code § Phar 10.02(15).

7. As a result of the above violations, MD Custom RX is subject to discipline pursuant to Wis. Stat. § 450.10(1)(a)2.

ORDER

1. The attached Stipulation is accepted.

2. Respondent MD Custom RX is REPRIMANDED.

3. The license to practice pharmacy issued to MD Custom RX (license number 8844-42) is LIMITED as follows:

a. Respondent shall not engage in the practice of sterile compounding of pharmaceutical products. In the event Respondent wished to engage in the practice of sterile compounding, Respondent shall petition the Board ninety (90) days in advance prior to engaging in the practice of sterile compounding

b. Respondent shall, upon request, without prior notice and at any time, allow any representative(s) of the Pharmacy Examining Board to inspect its premises and records for the purposes of ascertaining Respondent's compliance with the terms of this Order and any other rules of the Board. This limitation is permanent.

c. Respondent shall not engage in compounding of any pharmaceutical product without a patient-specific prescription, unless the prescription is for a refill of an existing prescription.

4. Within ninety (90) days from the date of this Order, MD Custom RX shall pay a FORFEITURE in the amount of $1,000.00.

5. Within ninety (90) days from the date of this Order, MD Custom RX shall pay COSTS of this matter in the amount of $1,550.00.

6. Payment 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, including but not limited to engaging sterile compounding of pharmaceutical products without approval from the Board 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. 8844-42) may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with payment of the forfeiture and costs.

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

WISCONSIN PHARMACY EXAMINING BOARD

by: _____ 6/3/15
A Member of the Board (DW) Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	STIPULATION
MD CUSTOM RX, RESPONDENT.	:	0004041

Division of Legal Services and Compliance Case Nos. 13 PHM 055, 14 PHM 057 and 14 PHM 075

Respondent MD Custom RX, 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. Respondent is not represented.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board (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 or Respondent's attorney, 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.

Monica Bozanski

Authorized Representative
MD Custom RX, Respondent
19035 W. Capital Dr., Ste. 105
Brookfield, WI 53045
License no. 8844-42

04-23-15
Date

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5/6/15
Date