

**BEFORE THE PHARMACY BOARD OF THE STATE OF IOWA**

<b>IN THE MATTER OF</b>  <b>EMPOWER PHARMACY</b> 7601 N. Sam Houston Pkwy Ste. 100 Houston, TX 77064  <b>RESPONDENT</b>	<b>CASE NO.: 2018-0123</b>  <b>SETTLEMENT AGREEMENT AND FINAL ORDER</b>
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**COMES NOW** the Iowa Board of Pharmacy (“Board”) and Empower Pharmacy (“Respondent”), pursuant to Iowa Code sections 17A.10(2), 272C.3(4), and 657 IAC 35.24 enter into this Settlement Agreement and Final Order (“Settlement Agreement”).

1. **Iowa License.** Respondent was most recently issued Iowa nonresident pharmacy license 5471 on February 16, 2022. Respondent’s Iowa nonresident pharmacy license is active, on probation, and will next expire on December 31, 2024.

2. **Jurisdiction.** The Board has jurisdiction in this matter pursuant to Iowa Code § 155A.

**A. STIPULATIONS**

3. **Practice Setting:** Respondent is an Iowa licensed nonresident pharmacy which operated in Houston, Texas and provided drugs to ultimate users in the state of Iowa during the time period relevant to these allegations. Respondent currently operates in Houston, Texas.

4. **Statement of Charges:** On March 5, 2024, the Iowa Board of Pharmacy filed a Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order alleging the Respondent was in violation of the Iowa Administrative Code rules set forth as follows:

a. Respondent violated 657 IAC 10.3 with failing to exercise professional judgment regarding the accuracy, validity, and authenticity of a prescription drug or medication order consistent with state laws, rules, and regulations;

b. Respondent violated 657 IAC 20.12 by compounding copies of Food and Drug Administration approved drugs without a clinically significant difference from those

approved drugs to meet a medical need for an individual patient as determined and authorized by the prescriber;

c. Respondent violated 657 IAC 8.5 by failing to ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs;

d. Respondent violated 657 IAC 20.3 by failing to follow the current revision of USP Chapter 795 standards and its incorporated references regarding nonsterile compounding; and

e. Respondent violated 657 IAC 20.4 by failing to follow the current revision of USP Chapter 797 standards and its incorporated references regarding sterile compounding.

5. Pursuant to agreement of the parties, Count I of the Statement of Charges is dismissed for purposes of settlement.

6. **Factual Circumstances:** On May 12, 2021, the Board issued a final order against the Respondent. The Respondent was cited for violating 657 IAC 20.12 and warned that future violations of laws or Board rules would result in disciplinary action. The Respondent was placed on three years of probation with the understanding Respondent would undergo at least one on-site inspection.

On November 28<sup>th</sup> and 29<sup>th</sup>, 2023, Board compliance officers inspected the Respondent's location in Houston, Texas. During the course of that inspection, compliance officers identified deficiencies related to sterile, nonsterile, and hazardous drug compounding. Subsequent investigation revealed the Respondent continues to compound drugs that are commercially available in spite of the Board's previous order. Further, during the November 2023 on-site inspection, Board compliance officers observed deficiencies related to Empower's hazardous drug compounding. Empower promptly responded to the Board's observations and immediately updated its practices to remediate the deficiencies that were based on new USP standards that had just been implemented. The Board has reviewed Empower's proposed remediations and agrees Empower's compliance with the proposed remediations will resolve the Board's concerns if properly implemented.

## **B. SETTLEMENT AGREEMENT**

7. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Settlement Agreement.

8. While Respondent denies the allegations, Respondent acknowledges that if the allegations are true, the allegations provide a basis for discipline under Iowa law.

9. To resolve this matter without proceeding to hearing, Respondent agrees to the following conditions:

- a. To pay a **civil penalty** in the amount of five thousand dollars(\$5,000); and
- b. The **Emergency Adjudicative Order** imposed on Respondent's nonresident pharmacy license is hereby vacated, subject to the following terms:
  - (i) Empower agrees not to ship any non-sterile compounded preparations into Iowa until it receives written confirmation from the Board that it has demonstrated full compliance with Iowa's statutes and rules through an on-site inspection performed by a mutually agreed upon third party. Empower will inform the Board when it has scheduled its inspection with the mutually agreed upon third party.
  - (ii) Empower agrees not to ship any sterile compounded preparations into Iowa until it receives written confirmation from the Board that it has demonstrated full compliance with Iowa's statutes and rules through an on-site inspection performed a mutually agreed upon third party. Empower will inform the Board when it has scheduled its inspection with the mutually agreed upon third party.

10. In entering this Settlement Agreement, Respondent acknowledges the following:

- a. This Settlement Agreement is subject to the approval of the Board and will have no force or effect if it is not accepted by the Board.
- b. Counsel for the State will present this Settlement Agreement to the Board *ex parte*.
- c. Empower has the right to be represented by counsel in this matter. During the negotiation of this settlement agreement, Empower was represented by Connie Diekema of the Finley Law Firm, P.C., Susan Dewey of Reed Smith, and Rachael Pontikes of Reed Smith.
- d. Empower understands it has an opportunity to be heard and to contest the allegations against it in a formal hearing before the Board and that, by waiving the formal hearing,

Empower waives its right to challenge the allegations against it and all attendant rights, including the right to seek judicial review of the Board's actions.

e. Empower has received and reviewed the investigative file in this matter.

f. Empower understands this Settlement Agreement will be part of its permanent licensure file and may be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

g. Empower voluntarily enters into this Settlement Agreement.

h. Failure to comply with the provisions of this Settlement Agreement shall be grounds for further disciplinary action pursuant to Iowa Code § 272C.3(2)(a).

i. Empower understands the Board will report this Settlement Agreement to the National Association of Boards of Pharmacy ("NABP") database. The report to the database will reflect the language included in this Order.

j. Empower understands it is responsible for all expenses incurred to comply with the conditions and requirements of this Settlement Agreement.

11. Respondent shall submit a copy of this Settlement Agreement to all licensing boards where Respondent holds a license, whether active or not, within **THIRTY days** of the date of the Board approval of this Settlement Agreement.

12. This Settlement Agreement constitutes discipline against Respondent pursuant to and in accordance with 657 Iowa Administrative Code 35.24 and is the final agency action in a contested case pursuant to Iowa Code § 17A.10.

13. Failure to comply with the provisions of this Settlement Agreement shall be grounds for further disciplinary action pursuant to Iowa Code section 272C.3(2)(a).

14. This Settlement Agreement shall not preclude the Board from taking additional action against Respondent should Respondent violate laws, rules, or standards of practice administered by the Board in the future.

15. This Settlement Agreement becomes a public record available for inspection and copying upon execution in accordance with the requirements of Iowa Code Chapters 17A, 22, and 272C.

16. This Settlement Agreement is subject to approval of the Board. If the Board fails to approve this agreement it shall be of no force or effect to either party.

17. The Board's approval of this Settlement Agreement shall constitute a **Final Order** of the Board.

### **C. FINAL ORDER**

**WHEREFORE**, the terms of this Settlement Agreement are agreed to by the Iowa Board of Pharmacy and the Respondent.

### **IT IS THEREFORE ORDERED,**

1. The Respondent shall pay a **civil penalty** in the amount of five thousand dollars (\$5,000).
2. The **Emergency Adjudicative Order** imposed on Respondent's nonresident pharmacy license is hereby vacated, subject to the following terms:
  - a. Empower agrees not to ship any non-sterile compounded preparations into Iowa until it receives written confirmation from the Board that it has demonstrated full compliance with Iowa's statutes and rules through an on-site inspection performed by a mutually agreed upon third-party. Respondent shall contact the Board when it has scheduled the onsite inspection with the mutually agreed upon third-party.
  - b. Empower agrees not to ship any sterile compounded preparations into Iowa until it receives written confirmation from the Board that it has demonstrated full compliance with Iowa's statutes and rules through an on-site inspection performed by a mutually agreed upon third-party. Respondent shall contact the Board when it has scheduled the onsite inspection with the mutually agreed upon third-party.


c. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.

d. Any documentation required to be submitted to the Board pursuant to this Order should be emailed to [Amanda.Woltz@iowa.gov](mailto:Amanda.Woltz@iowa.gov) by the specified deadline unless otherwise directed.

3. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC 36.

**FOR THE RESPONDENT:**

Voluntarily agreed to and accepted by Empower Pharmacy on 4th day of December, this 2024.

  
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By  
On Behalf of  
Empower Pharmacy, Respondent

**FOR THE IOWA BOARD OF PHARMACY:**

Voluntarily agreed to and accepted by the **IOWA BOARD OF PHARMACY** on this 7th day of January, 2025.

  
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Chairperson