

BEFORE THE PHARMACY BOARD OF THE STATE OF IOWA

<p>IN THE MATTER OF</p> <p>EMPOWER PHARMACY 7601 N. Sam Houston Parkway Ste. 100 Houston, TX 77064</p> <p>RESPONDENT</p>	<p>CASE NO.: 2018-0123</p> <p>COMBINED NOTICE OF HEARING, STATEMENT OF CHARGES, AND EMERGENCY ADJUDICATIVE ORDER</p>
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COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order against Empower Pharmacy (“Respondent”), pursuant to Iowa Code sections 17A.12(2), 17A.18(3), 17A.18A, 272C.3(1)(e), and 657 IAC 35.35.

A. TIME, PLACE AND NATURE OF HEARING

1. **Hearing.** A contested case hearing shall be held on April 12, 2024, before the Board. The hearing shall begin at 8:00 a.m. and shall be located in the conference room at the office of the Iowa Board of Pharmacy, 6200 Park Avenue, Ste. 100, Des Moines, Iowa 50319.

2. **Scheduling Conference.** A scheduling conference to schedule pre-hearing deadlines shall be held by telephone on March 28, 2024 at 9:00 a.m. before Administrative Law Judge Rachel Morgan from the Iowa Department of Inspections, Appeals and Licensing at the following conference line, 855-638-5575. Board rules on prehearing conferences may be found at 657 Iowa Administrative Code 35.22.

3. **Answer.** Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges you are permitted by 657 IAC 36.16 to file an Answer. Should you file an Answer, please note whether you will request a continuance of the date and time of the hearing.

4. **Filing of Pleadings.** Pleadings shall be filed with the Board at the following address:

Iowa Board of Pharmacy, 6200 Park Avenue, Ste. 100, Des Moines, Iowa 50319, by email to Amanda.woltz@iowa.gov, or electronically using the Administrative Electronic Document Management System (adminhearings.iowa.gov/efile/).

5. **Presiding Officer.** The Board shall serve as presiding officer at the contested case hearing, but the Board hereby delegates to an Administrative Law Judge from the Department of Inspections, Appeals and Licensing, the authority to make initial rulings on prehearing matters, and requests the Administrative Law Judge be present to assist and advise the Board at hearing.

6. **Prehearing Conference.** Any party may request a prehearing conference to discuss evidentiary issues related to the hearing in accordance with 657 IAC 35.22.

7. **Hearing Procedures.** The procedural rules governing the conduct of the hearing are found at 657 IAC 35.35. At the hearing, you may appear personally or be represented by legal counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at hearing. If you need to request an alternative time or date for hearing, you must comply with the requirements of 657 IAC 35.23. The hearing may be open to the public or closed to the public at the discretion of the Respondent.

8. **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: Lindsey L. Browning, Assistant Attorney General, Office of the Iowa Attorney General 1305 E. Walnut Street, 2nd Floor, Des Moines, Iowa 50319.

9. **Communications.** You may not contact Board members in any manner, including by phone, letter, facsimile, in person or e-mail, about this Notice of Hearing and Statement of Charges.

Board members may 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 and serve upon all parties in the case. You may contact Amanda Woltz, Executive Officer, Iowa Board of Pharmacy, at 515-281-6674 or Amanda.Woltz@iowa.gov, or Assistant Attorney General Lindsey L. Browning at 515-281-3441 or lindsey.browning@ag.iowa.gov.

B. LEGAL AUTHORITY AND JURISDICTION

10. **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.

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

12. **Legal Authority**. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code § 155A and 657 Iowa Administrative Code 36.

13. **Default**. The Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code § 17A.12(3) and Iowa Administrative Code 35.27.

C. STATEMENT OF CHARGES

COUNT I

14. Respondent is charged under 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 federal and state laws, rules, and regulations.

COUNT II

15. Respondent is charged under 657 IAC 20.12 with 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.

COUNT III

16. Respondent is charged under 657 IAC 8.5 with failing to ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs.

COUNT IV

17. Respondent is charged under 657 IAC 20.3 with failing to follow the current revision of USP Chapter 795 standards and its incorporated references regarding nonsterile compounding.

COUNT V

18. Respondent is charged under 657 IAC 20.4 with failing to follow the current revision of USP Chapter 797 standards and its incorporated references regarding sterile compounding.

D. FINDINGS OF FACT

19. **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.

20. **Procedural Background.** 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. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21. **Present Circumstances.**

E. SETTLEMENT

22. This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code 35.24. If you are interested in pursuing settlement of this matter, please contact the Assistant Attorney General identified above.

F. PROBABLE CAUSE FINDING

23. On March 5, 2024, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

G. CONCLUSIONS OF LAW

24. Iowa Code § 155A.2 states in pertinent part,

(i)t is the purpose of this chapter [in establishing the Iowa Board of Pharmacy] to promote, preserve, and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacists...engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized.

Iowa Code § 155A.2(1).

25. In furtherance of its purpose as cited above, the Board

may...revoke, *restrict*, cancel or suspend a license...if the (B)oard finds that the...licensee has done any of the following:

(1) violated any provision of this chapter or any rules of the board adopted under this chapter.

Iowa Code § 155A.12(1)(emphasis added).

26. Additionally, pursuant to statute, the Board may take emergency action “as is necessary to prevent or avoid the immediate danger to the public health, safety, or welfare...”. Iowa Code § 17A.18A(2).

H. ORDER

IT IS THEREFORE ORDERED:

A. [REDACTED]

[REDACTED]

[REDACTED]

B. [REDACTED]

[REDACTED]

C. [REDACTED]

■ [REDACTED]

[REDACTED]

■ [REDACTED]

[REDACTED]

■ [REDACTED]

[REDACTED]

D. In order to protect the ultimate users of Respondent’s more than 65,000 compounded products dispensed into in the State of Iowa, the Board now takes action to restrict the Respondent’s ability to compound drugs for Iowans.

E. Accordingly, Respondent’s Iowa nonresident pharmacy license is hereby **INDEFINITELY RESTRICTED** effective March 15, 2024.



Chairperson
Iowa Board of Pharmacy

Copy to:
Lindsey L. Browning
Assistant Attorney General
Office of the Iowa Attorney General
1305 E. Walnut Street
Ste. 100
Des Moines, Iowa 50319
Lindsey.browning@ag.iowa.gov

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-0233. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).