

**BEFORE THE IOWA BOARD OF PHARMACY**

<p>RE: Pharmacy License of</p> <p><b>DANIEL PHARMACY</b> License No. 752 Respondent</p>	<p>CASE NO. 2022-0007</p> <p><b>SETTLEMENT AGREEMENT AND FINAL ORDER</b></p>
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Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4), and 657 Iowa Administrative Code (IAC) 35.24, the Iowa Board of Pharmacy (“Board”) and Daniel Pharmacy (“Respondent”) enter into the following Settlement Agreement and Final Order (“Order”) to settle a contested case currently pending before the Board.

The allegations contained in the Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board filed a Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order on June 28, 2022.
2. The Board has jurisdiction over Respondent and the subject matter of this proceeding.
3. The factual circumstances contained in the Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order are hereby incorporated into this Order. Respondent acknowledges that the allegations contained in the factual circumstances in the Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order. Respondent further acknowledges that any confidential factual circumstances contained in the Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order, by virtue of their incorporation into this Order, are now public and are available for inspection and copying in accordance with Iowa Code chapters 22 and 272C.
4. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board’s actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
5. Respondent acknowledges that it has the right to be represented by counsel on this matter.
6. Respondent agrees that the State’s counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

7. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

8. This Order shall be part of Respondent's permanent record and shall 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.

9. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

10. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

11. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

**IT IS THEREFORE ORDERED:**

12. Respondent is **RESTRICTED** from compounding with hazardous drugs until further order of the Board. If Respondent wishes to have this restriction lifted it must submit a request to the Board. When submitting a request, Respondent has the burden to demonstrate that compounding will be performed in full compliance with USP Chapter 800. Respondent understands and agrees that, unless and until the restriction is lifted, a restriction will remain on the license indefinitely.

13. Respondent's pharmacy license is hereby placed on **PROBATION** for a period of two (2) years, subject to the following terms:

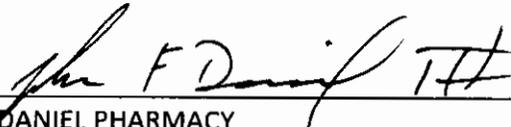
- a. On a quarterly basis, Respondent shall submit a report to the Board that includes all of the following information: a report listing all compounded preparations compounded by Respondent and dispensed to Iowa patients for that quarter; any recalls initiated in that quarter; and any complaints pertaining to the quality or safety of compounded preparations. The quarterly reports are due by March 5<sup>th</sup> (reporting on December—February), June 5<sup>th</sup> (report on March—May), September 5<sup>th</sup> (reporting on June—August), and December 5<sup>th</sup> (reporting on September—November). Upon receipt, the Board will select prescriptions to review and notify Respondent of the selected prescriptions. Within 72 hours, Respondent shall submit all of the following for each prescription selected: a copy of the prescription, a copy of the prescription label, the compounding record, and the certificates of analysis for the ingredients utilized.

- b. 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.
- c. Respondent shall appear before the Board upon request for purposes of evaluating performance of the probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.

14. 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.

By the signature below, signatory acknowledges they are authorized to sign this Settlement Agreement and Final Order on behalf of Respondent.

10-18-22  
Date

  
DANIEL PHARMACY  
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on  
October 25, 2022.

  
Kathryn Stone  
Chairperson  
Iowa Board of Pharmacy

**BEFORE THE IOWA BOARD OF PHARMACY**

RE: Pharmacy License of  <b>DANIEL PHARMACY</b> License No. 752 Respondent	CASE NO. 2022-0007  <b>NOTICE OF HEARING, STATEMENT OF CHARGES, AND EMERGENCY ADJUDICATIVE ORDER</b>
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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 Daniel Pharmacy (“Respondent”), 1114 Central Ave, Fort Dodge IA 50501, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), 17A.18A, and 272C.3(1)(e), and 657 Iowa Administrative Code (IAC) 35.6, 35.7, and 35.35.

**A. TIME, PLACE, AND NATURE OF HEARING**

Hearing. A disciplinary contested case hearing shall be held on August 23, 2022, before the Board. The hearing shall begin at 1:00 p.m. and will be held in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8<sup>th</sup> St, Ste E, Des Moines, IA 50309. You may choose to attend the hearing in-person at the Board office or may attend electronically through the Zoom platform. Contact the Board office to obtain participation instructions if you wish to attend electronically.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order you may file an Answer pursuant to 657 IAC 35.16. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order.

Filing of Pleadings. Pleadings shall be filed with the Board either by e-mail, if done in compliance with 657 IAC 35.17(2), to [Amanda.Woltz@iowa.gov](mailto:Amanda.Woltz@iowa.gov), or by mail/delivery to the following address: Iowa Board of Pharmacy, 400 SW 8<sup>th</sup> St, Ste E, Des Moines IA 50309.

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 and Appeals the authority to make initial rulings on prehearing matters and requests the administrative law judge be present to assist and advise the Board at the contested case hearing.

Hearing Procedures. The procedural rules governing the conduct of the contested case hearing, including prehearing matters, are found at 657 IAC chapter 35. At the hearing, you may appear personally or be represented by 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 the hearing. The hearing may be open to the public or closed to the public at your discretion, pursuant to Iowa Code section 272C.6(1) and 657 IAC 35.25(10).

Prosecution. The Office of Attorney General of Iowa is responsible for representing the public interest (the State) in this proceeding. Counsel for the State in this matter is Assistant Attorney General Laura Steffensmeier. Ms. Steffensmeier can be reached by phone at (515) 281-6690. Copies of pleadings should be provided to counsel for the State either by email to [Laura.Steffensmeier@ag.iowa.gov](mailto:Laura.Steffensmeier@ag.iowa.gov), or by mail/delivery to the following address:

Laura Steffensmeier  
Assistant Attorney General  
Hoover State Office Building—2<sup>nd</sup> Floor  
1305 E Walnut St  
Des Moines IA 50319

Communications. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file and serve upon all parties in the case.

## **B. LEGAL AUTHORITY AND JURISDICTION**

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 155A, and 272C.

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you pursuant to Iowa Code sections 155A.15(2) and 272C.3, and 657 IAC 8.3 and 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.27.

## **C. STATEMENT OF CHARGES**

### **COUNT I**

Respondent is charged under 657 IAC 36.6(21) with violating a rule of the Board, specifically 657 IAC 8.5(11), which requires compliance with USP Chapter 800 standards for handling hazardous drugs.

## COUNT II

Respondent is charged under 657 IAC 36.6(21) with violating a rule of the Board, specifically 657 IAC 20.3, which requires compliance with USP Chapter 795 standards when compounding nonsterile preparations.

### D. FACTUAL CIRCUMSTANCES

1. Respondent's pharmacy license number 752 is currently active through December 31, 2022.
2. Respondent had previously received a waiver for the requirements of USP Chapter 800 pertaining to facilities and engineering controls, which expired on April 30, 2021.
3. In December 2021, Respondent was observed to be non-compliant with USP Chapter 800 standards related to compounding with hazardous drugs. Respondent was given thirty days to come into compliance.
4. In January 2022, Respondent was observed to still be non-compliant with USP Chapter 800 related to compounding with hazardous drugs.

### E. EMERGENCY ADJUDICATIVE ORDER

#### FINDINGS OF FACT

The Board finds sufficient evidence to support each factual circumstance identified in section D, above.

#### CONCLUSIONS OF LAW

Based on these findings of fact, the Board concludes Respondent has violated the laws cited in Counts I and II, identified in section C, above.

#### POLICY REASONS

Respondent has had ample time to comply with applicable standards for compounding with hazardous drugs, but continues to be non-compliant. Respondent's continued ability to compound with hazardous drugs in a non-compliant manner poses an immediate danger to the public health, safety, and welfare. Respondent cannot be allowed to continue compounding with hazardous drugs in a non-compliant manner.

#### ORDER

Respondent's pharmacy license is **RESTRICTED** from compounding with hazardous drugs until such time as it receives written permission from the Board to resume compounding with hazardous drugs. Respondent shall contact the Board when it believes it is ready to resume compounding with hazardous drugs in full compliance with all applicable requirements. The

Board will perform an inspection to determine compliance and will provide written permission to resume compounding with hazardous drugs if and when Respondent is compliant with all applicable requirements.

**F. SETTLEMENT**

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 35.24. To cancel a scheduled hearing, an executed settlement agreement must be received by the Board at least three (3) business days prior to the scheduled hearing. If you are interested in pursuing settlement in this matter, please contact the Assistant Attorney General identified above.

**G. FINDING OF PROBABLE CAUSE**

On June 28, 2022, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing, Statement of Charges, and Emergency Adjudicative Order.

A handwritten signature in cursive script that reads "Kathryn Stone". The signature is written in black ink and is positioned above a horizontal line.

Chairperson  
Iowa Board of Pharmacy

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).