

**BEFORE THE IOWA BOARD OF PHARMACY**

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Re:	)	CASE NO. 2015-108
Pharmacy License of	)	
	)	<b>SETTLEMENT AGREEMENT</b>
<b>PHARMACY MATTERS</b>	)	<b>AND FINAL ORDER</b>
License No. 1449	)	
Respondent.	)	

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Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy and Pharmacy Matters ("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 and Statement of Charges on May 4, 2016.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. Respondent has chosen not to contest the allegations in the Notice of Hearings and Statement of Charges, but acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
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. This Order shall not be binding as to any new complaints received by the Board.

10. 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.

11. 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.

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

**IT IS THEREFORE ORDERED:**

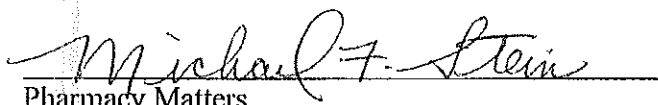
13. Respondent's license is hereby placed on PROBATION for a period of four (4) years subject to the following terms:

- a. Respondent shall pay a CIVIL PENALTY in the amount of twenty-five hundred dollars (\$2500) within sixty (60) days of Board approval of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.
- b. Within thirty (30) days of Board approval of this Order, the Respondent shall take all corrective action necessary to remedy all deficiencies identified in the inspections of May and June 2015, including developing and fully implementing policies and procedures concerning deliveries, a continuous quality improvement program, returns of unit dose medications, and emergency schedule II controlled substances prescriptions. Documentation of the corrective action, including the new policies and procedures, should be mailed to the Board office within thirty (30) days of Board approval of this Order. Such documentation should be mailed to the Iowa Board of Pharmacy, Attn: Debbie Jorgenson, 400 SW Eighth Street, Suite E, Des Moines, IA 50309.
- c. Respondent shall perform monthly audits of its controlled substances. All audits shall be documented and available to the Board upon request.
- d. Respondent shall complete self-inspections on a quarterly basis each year and submit documentation of each self-inspection to the assigned Board compliance officer no later than March 5, June 5, September 5, and December 5 of each calendar year during the probationary period. Board compliance officers may conduct on-site inspections at any time. Respondent shall work with Board compliance officers to ensure any deficiencies uncovered during any self-inspection or on-site inspection are corrected in a timely fashion. Respondent's failure to correct deficiencies in a timely fashion shall be considered a violation of this Order.

- e. 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.
- f. The Board may, in its sole discretion, decrease the frequency of the required audits or self-inspections during the probationary period based on satisfactory performance by Respondent.

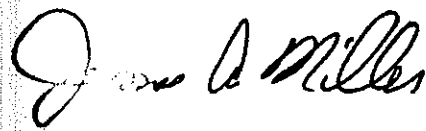
14. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 147, 155A, and 272C and 657 IAC 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 22 day of December, 2016.

  
\_\_\_\_\_  
Pharmacy Matters  
Respondent

By this signature, Michael F. Stein acknowledges s/he is the Pharmacist for Pharmacy Matters and is authorized to sign this Settlement Agreement and Final Order on behalf of Pharmacy Matters.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 4<sup>th</sup> day of January, ~~2016~~ 2017.

  
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Chairperson  
Iowa Board of Pharmacy

Copies to:

Meghan Gavin  
Assistant Attorney General  
Licensing & Administrative Law Division  
Iowa Department of Justice

Hoover Building, 2<sup>nd</sup> Floor  
Des Moines, IA 50319  
ATTORNEY FOR THE STATE

Jason Snyder  
Paduano & Weintraub LLP  
1251 Avenue of the Americas  
Ninth Floor  
New York, NY 10020  
ATTORNEY FOR RESPONDENT

**BEFORE THE IOWA BOARD OF PHARMACY**

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Re:	)	CASE NO. 2015-108
Pharmacy License of	)	
	)	<b>NOTICE OF HEARING AND</b>
<b>PHARMACY MATTERS</b>	)	<b>STATEMENT OF CHARGES</b>
License No. 1449	)	
Respondent.	)	

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**COMES NOW** the Iowa Board of Pharmacy and files this Notice of Hearing and Statement of Charges against Pharmacy Matters LTC 3526 Dolphin Dr. SE, Iowa City, Iowa 52244 pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)(e), and Iowa Administrative Code rules 657—35.5 and 36.5. Respondent's Iowa pharmacy license number 1449 is currently active through December 31, 2016.

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

Hearing. A disciplinary contested case hearing shall be held on June 29, 2016, before the Board. The hearing shall be held during the morning session beginning at 9:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.11. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

Filing of Pleadings. Pleadings shall be filed with the Board at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

Pre-hearing Conference. Any party may request a prehearing conference in accordance with Iowa Administrative Code rule 657—35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at Iowa Administrative Code chapter 657—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. If you need to request an alternative time or date for the hearing, you must comply with the requirements in Iowa Administrative Code rule 657—35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Meghan Gavin  
Assistant Attorney General  
Iowa Attorney General's Office  
2<sup>nd</sup> Floor, Hoover State Office Building  
Des Moines, Iowa 50319

Ms. Gavin can also be reached by phone at (515) 281-6736 or by e-mail at [Meghan.Gavin@iowa.gov](mailto:Meghan.Gavin@iowa.gov).

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. 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 with the Board office 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, 147, 155A, and 272C (2015).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 147, 155A, and 272C, and Iowa Administrative Code chapter 657—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 Iowa Administrative Code rule 657—35.21.

## **C. CHARGES**

### **COUNT I**

#### **FAILURE TO KEEP AND MAINTAIN RECORDS**

Respondent is charged with failing to keep and maintain records as required by law, specifically for failing to keep supplier invoices and for failing to have a responsible person clearly record the date of receipt of controlled substances on supplier invoices in violation of Iowa Administrative Code rule 657—8.9(1), pursuant to Iowa Code section 155A.15(2)(c), (h) and Iowa Administrative Code rule 657—36.1(4)(u) and (ac).

### **COUNT II**

#### **FAILURE TO MAINTAIN A CONTINUOUS QUALITY IMPROVEMENT PROGRAM**

Respondent is charged with failing to maintain a continuous quality improvement program in violation of Iowa Code sections 147.55(9) and 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 8.3(1),<sup>1</sup> 8.26, and 36.1(4)(u).

### COUNT III

#### FAILURE TO HAVE SUFFICIENT POLICIES AND PROCEDURES

Respondent is charged with failing to have sufficient policies and procedures in violation of Iowa Code section 147.55(9) and 155A.15(2)(c), (h) and 657 Iowa Administrative Code rules 8.3(1), and 36.1(4)(u).

### COUNT IV

#### UNETHICAL BEHAVIOR OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC

Respondent is charged with engaging in unethical behavior or practice harmful or detrimental to the public in violation of Iowa Code section 155A.15(2)(c) and 657 Iowa Administrative Code rule 36.1(4)(c).

### D. FACTUAL CIRCUMSTANCES

1. At all times, the Respondent was an Iowa licensed pharmacy doing business at 3526 Dolphin Dr. SE, Iowa City, IA 52244.
2. A routine inspection of Pharmacy Matters LTC was conducted on May 26, 2015.
3. During the inspection, a number of deficiencies were noted, including failure to have a permanent log, operating with an expired controlled substance registration, failing to mark schedule III, IV, and V controlled substances as to who received them, failure to maintain a bulk compounding log, failure to have policies and procedures on delivery, not properly handling returns of unit dose medications, and failure to properly handle emergency schedule II controlled substances prescriptions.
4. A follow-up visit on June 2, 2015 revealed that the pharmacy had not established a continuous quality improvement program.

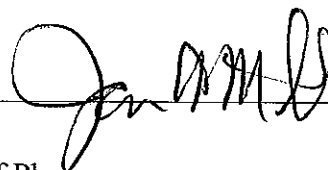
### E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at Iowa Administrative Code rule 657—36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Meghan Gavin at (515) 281-6736.

### F. FINDING OF PROBABLE CAUSE

On this 4<sup>th</sup> day of May, 2016, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

<sup>1</sup> This citation references the rule in place at the time of the alleged violation. This rule has since been amended. Please see the current version of Iowa Administrative Code rule 657—8.3(2), 8.3(3).



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Chairperson  
Iowa Board of Pharmacy

Copy to:

Meghan Gavin  
Assistant Attorney General  
Hoover Building, 2<sup>nd</sup> Floor  
1305 E. Walnut St.  
Des Moines, IA 50319

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).