BEFORE THE IOWA BOARD OF PHARMACY

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

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

<u>Hearing.</u> 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. 8th 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.

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

<u>Presiding Officer.</u> 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.

<u>Pre-hearing Conference.</u> 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.

<u>Prosecution.</u> 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
2nd 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.

<u>Communications</u>. 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

<u>Jurisdiction</u>. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2015).

<u>Legal Authority</u>. 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.

<u>Default.</u> 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), 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 h day of April, 2016, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

¹ 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).

Chairperson

Iowa Board of Pharmacy

Copy to:

Meghan Gavin Assistant Attorney General Hoover Building, 2nd 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).