

BEFORE THE IOWA BOARD OF PHARMACY

Re:) CASE NO. 2015-123
Pharmacy License of)
) **MODIFICATION ORDER**
ANKENY PHARMACY)
License No. 1475)
Respondent.)

The Settlement Agreement and Final Order in the above-captioned matter dated May 4, 2016, is modified as follows:

1. The minimum frequency of the required audits under Paragraph 14b shall be reduced from monthly to quarterly.
2. The minimum frequency of the required self-inspections under Paragraph 14c shall be reduced from quarterly to every six months.

IT IS HEREBY ORDERED that Paragraphs 14b and 14c are so modified.

Dated this 19th day of September, 2018.



Andrew Funk, Pharm.D., Executive Director
IOWA BOARD OF PHARMACY

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-123
Pharmacy License of)	
)	SETTLEMENT AGREEMENT
ANKENY PHARMACY)	AND FINAL ORDER
License No. 1475)	
Respondent.)	

Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4) (2015), and 657 IAC 36.6, the Iowa Board of Pharmacy ("Board") and Ankeny 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 and Statement of Charges on January 12, 2016.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. The Factual Circumstances in the Statement of Charges are explained as follows: Respondent asserts that pharmacy technicians performed only an initial check of strips of med paks, but a pharmacist always performed the final check. Respondent asserts that the rules do not specifically require review of each med pak, but Respondent began reviewing each individual med pak after the inspection. There is no evidence of any medication errors in the med paks dispensed by Respondent. Respondent began retaining documentation of final med pak verification after the inspection. After the inspection, Respondent ceased re-using comingled drugs from returned med paks. Respondent asserts the discrepancies identified in the controlled substances audit are largely attributed to dispensing errors traced to one pharmacist employee who was not the Pharmacist in Charge and Respondent's purchases from Mercy Specialty Pharmacy when it ceased doing business.
4. Respondent denies the allegations contained in Counts I, II, IV, V, and VI, but in the interest of settlement has chosen not to contest the charges. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.
5. 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.
6. Respondent acknowledges that it has the right to be represented by counsel on this matter.

7. 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.

8. 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.

9. 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.

10. This Order shall not be binding as to any new complaints received by the Board.

11. 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.

12. 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.

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

IT IS THEREFORE ORDERED:

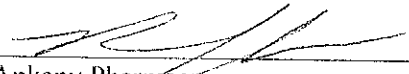
14. Respondent's license is hereby placed on **PROBATION** for a period of four (4) years subject to the following terms:

- a. Respondent shall pay a **CIVIL PENALTY** in the amount of two-thousand five hundred dollars (\$2,500) 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. Respondent shall continue to perform monthly audits of its controlled substances. All audits shall be documented and available to the Board upon request.
- c. 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.

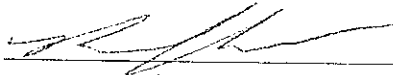
- d. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.
- e. The Board may, in its discretion, decrease the frequency of the required audits or self-inspections during the probationary period based on satisfactory performance by Respondent.

15. 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.

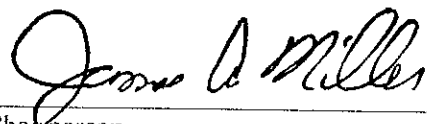
This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 27 day of April, 2016.



Ankeny Pharmacy
Respondent

By this signature,  acknowledges s/he is the owner for Ankeny Pharmacy and is authorized to sign this Settlement Agreement and Final Order on behalf of Ankeny Pharmacy.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 4th day of May, 2016.



Chairperson
Iowa Board of Pharmacy

Copies to:

Laura Steffensmeier
Assistant Attorney General
Licensing & Administrative Law Division
Iowa Department of Justice

Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

Rebecca Brommel
Brown Winick
666 Grand Avenue
Suite 2000 Ruan Center
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2015-123
Pharmacy License of)	
)	NOTICE OF HEARING AND
ANKENY PHARMACY)	STATEMENT OF CHARGES
License No. 1475)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Ankeny Pharmacy ("Respondent"), 1325 SW Oralabor Road, Suite 200, Ankeny, IA 50023, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.5 and 36.5. Respondent's Iowa pharmacy license number 1475 is currently active through December 31, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on March 8, 2016, before the Board. The hearing shall be held during the afternoon session beginning at 1:00 p.m. and shall be located in the Northwestern Room--345 at the Iowa Memorial Union, 125 N. Madison Street, Iowa City, Iowa 52242.

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. 8th 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 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 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 657 IAC 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:

Laura Steffensmeier
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at laura.steffensmeier@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 657 IAC 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 35.21.

C. CHARGES

COUNT I

IMPROPER DELEGATION TO PHARMACY TECHNICIANS

Respondent is charged with permitting pharmacy technicians to perform final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order in violation of Iowa Code section 155A.33, and 657 IAC 3.21(1) and 3.23(1), pursuant to Iowa Code section 155A.15(2)"c", and 657 IAC 36.1(4)"l" and "u".

COUNT II

FAILURE TO PROPERLY VERIFY AND DOCUMENT

Respondent is charged with failing to provide, document, and retain a record of the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the

patient's representative in violation of 657 IAC 8.3(7), pursuant to Iowa Code section 155A.15(2)"c" and 657 IAC 36.1(4)"u".

COUNT III

MISUSE OF RETURNED PATIENT MED PAKS

Respondent is charged with returning drugs dispensed in patient med paks to pharmacy stock in violation of 657 IAC 22.5(2)"c", pursuant to Iowa Code section 155A.15(2)"c" and 657 IAC 36.1(4)"u".

COUNT IV

FAILURE TO MAINTAIN ACCURATE PERPETUAL INVENTORY

Respondent is charged with failing to maintain an accurate perpetual inventory of Schedule II controlled substances in violation of 657 IAC 10.33, pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

COUNT V

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 657 IAC 8.9(1), pursuant to Iowa Code section 155A.15(2)"c" and 657 IAC 36.1(4)"u" and "ac".

COUNT VI

FAILURE TO MAINTAIN ANNUAL INVENTORY OF CONTROLLED SUBSTANCES

Respondent is charged with failing to maintain an annual inventory of controlled substances in violation of 657 IAC 10.35, pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

D. FACTUAL CIRCUMSTANCES

1. Respondent utilized pharmacy technicians to perform final verification of strips of med paks for long-term care facilities.
2. When pharmacists were utilized to perform final verification of strips of med paks, the med paks were not verified individually.
3. Respondent did not retain documentation of pharmacist final verification for the strips of med paks.
4. Respondent disassembled returned med paks in order to re-use the previously dispensed medication.
5. An audit of Respondent's inventory of controlled substances from January 2014 through September 2015 revealed shortages or overages for a majority of the drugs audited.
6. An audit of Respondent's records of controlled substances from January 2014 through September 2015 revealed the following:

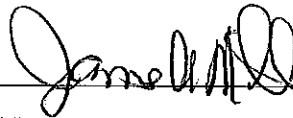
- a. Respondent did not maintain proper records for transfers of controlled substances to and from other pharmacies.
 - b. Respondent's perpetual inventory of Schedule II controlled substances did not match billing or dispensing records.
 - c. Respondent did not have invoices for approximately 6,000 tablets of Lorazepam.
 - d. Several of Respondent's invoices for controlled substances were not signed or dated by the person responsible for receiving the order.
7. Respondent could not produce its most recent annual inventory of controlled substances.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

F. FINDING OF PROBABLE CAUSE

On this 12th day of January, 2016, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
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).