BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacy License of **HY-VEE PHARMACY 1068** License No. 811 Respondent.	))))))	CASE NO. 2015-110 **NOTICE OF HEARING AND STATEMENT OF CHARGES**

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Hy-Vee Pharmacy 1068 ("Respondent"), 800 N Second Street, Cherokee, IA 51012, 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 811 is currently active through December 31, 2015.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on January 12, 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.

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
FAILURE TO ESTABLISH EFFECTIVE CONTROLS AGAINST DIVERSION

Respondent is charged with failing to establish effective controls against diversion of prescription drugs in violation of 657 IAC 6.7 and 10.15, pursuant to Iowa Code section 155A.15(2)"i" and 657 IAC 36.1(4)"u".

COUNT II
FAILURE TO KEEP RECORDS

Respondent is charged with failing to keep records as required by law, specifically supplier invoices, in violation of 657 IAC 8.9(1), pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

COUNT III
FAILURE TO MAINTAIN RECORDS

Respondent is charged with failing to properly maintain records, specifically 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)"h" and 657 IAC 36.1(4)"u" and "ac".

COUNT IV
FAILURE TO MAINTAIN SEPARATE RECORDS

Respondent is charged with failing to maintain records of controlled substances listed in Schedules III, IV, and V separately from all other records or in such a form that the required information is readily retrievable from the ordinary business records, in violation of 657 IAC 10.34(2), pursuant to Iowa Code section 155A.15(2)"h" and 657 IAC 36.1(4)"u" and "ac".

D. FACTUAL CIRCUMSTANCES

1. An audit of Respondent's records from September 2013 through April 2015 indicated the following shortages: approximately 5800 tablets of hydrocodone-containing products, approximately 830 tablets of Lorazepam, and approximately 469 tablets of Diazepam.

2. Respondent attributes the losses to employee pilferage.

3. For the same audit period, Respondent did not have invoices for the following: approximately 25,000 tablets of hydrocodone-containing products, approximately 30,300 tablets of Lorazepam, and approximately 2,000 tablets of Diazepam.

4. A review of Respondent's 2015 invoices for controlled substances revealed the following:

   a. For multiple months, Respondent's invoices for controlled substances in Schedules III, IV, and V were not maintained separately from other prescription drug invoices.

   b. In one month, several of Respondent's invoices for controlled substances were not signed or dated by the person responsible for receiving the order.

   c. Respondent had possession of two original controlled substances invoices for another Hy-Vee pharmacy.

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 4th day of November, 2015, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

James Miller, 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).

BEFORE THE IOWA BOARD OF PHARMACY

Re: Pharmacy License of **HY-VEE PHARMACY 1068** License No. 811 Respondent.	))))))	CASE NO. 2015-110 **SETTLEMENT AGREEMENT AND FINAL ORDER**

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 Hy-Vee Pharmacy 1068 ("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 November 4, 2015.

2. The Board has jurisdiction over the parties and the subject matter of these proceedings.

3. Respondent denies the allegations contained in the Statement of Charges, but in the interest of settlement has chosen not to contest the allegations. Respondent 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 three (3) years subject to the following terms:

a. Respondent shall pay a **CIVIL PENALTY** in the amount of five thousand dollars ($5,000) within thirty (30) 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 perform monthly audits of its controlled substances. All audits should be documented and available to the Board upon request.

c. Respondent shall undergo quarterly inspections by a Board compliance officer. Respondent shall work with Board compliance officers to ensure any deficiencies uncovered during the inspections 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 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 10 day of December, 2015.

Makenzie Aesoph

Hy-Vee Pharmacy 1068
Respondent

By this signature, Makenzie Aesoph acknowledges s/he is the Pharmacy Manager for Hy-Vee Pharmacy 1068 and is authorized to sign this Settlement Agreement and Final Order on behalf of Hy-Vee Pharmacy 1068.

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of January, 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

Edwin McIntosh
Dorsey & Whitney LLP
801 Grand, Suite 4100
Des Moines, IA 50309
ATTORNEY FOR RESPONDENT