

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2014-57
Pharmacist License of)	
)	NOTICE OF HEARING AND
MARY MCMILLAN)	STATEMENT OF CHARGES
License No. 19740)	
Respondent.)	

COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against Mary McMillan (“Respondent”), 6113 Golden Rd., Elgin, Iowa 52141, pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent’s Iowa pharmacist license number 19740 is currently active and expires on June 30, 2016.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on November 18 2014, before the Iowa Board of Pharmacy. 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 400 S.W. 8th Street, Des Moines, Iowa.

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 pre-hearing matters, and be present to assist and advise the Board at the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 IAC 35.19. 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 147, 155A, and 272C (2013).

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 under 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 PROPERLY DISPOSE OF EXPIRED CONTROLLED SUBSTANCES

Respondent is charged with failing to properly dispose of expired drugs, including controlled substances, in violation of 657 IAC 7.2(12), 8.8, and 10.18, pursuant to Iowa Code sections 147.55(9), 155A.12(1), (4), and (5), and 657 IAC 36.1(4)“u”.

Count II

FAILURE TO MAINTAIN COMPLETE AND ACCURATE RECORDS OF PURCHASES AND DISPOSAL OF CONTROLLED SUBSTANCES

Respondent is charged with failing to maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act in violation of 657 IAC 7.2(13), 10.18, and 10.34(4), pursuant to Iowa Code sections 147.55(9), 155A.12(1), (4), and (5), and 657 IAC 36.1(4)“u”.

Count III

FAILURE TO MAINTAIN ADEQUATE CONTROL OVER AND ACCOUNTABILITY FOR CONTROLLED SUBSTANCES

Respondent is charged with failing to maintain adequate control over and accountability for controlled substances in violation of Iowa Code sections 124.308 and 124.402(1), and 657 IAC 7.2(13), pursuant to Iowa Code sections 155A.12(1), (4), and (5), and 657 IAC 36.1(4)“u” and “ac”.

Count IV
FAILURE TO KEEP AND MAINTAIN RECORDS REQUIRED BY THE
CONTROLLED SUBSTANCES ACT

Respondent is charged with failing to keep and maintain records required by Iowa Code section 124.306, a provision of the Controlled Substances Act, in violation of 657 IAC 7.2(13) and 10.34(4), pursuant to Iowa Code sections 155A.12(1), (4), and (5), and 657 IAC 36.4(1) "u" and "ac".

Count V
FAILURE TO MAINTAIN A PERPETUAL INVENTORY

Respondent is charged with failing to maintain a perpetual inventory for Schedule II controlled substances, in violation of 657 IAC 7.2(13) and 10.33, pursuant to Iowa Code sections 147.55(9), 155A.12(1), (4), and (5), and 657 IAC 36.1(4) "u" and "ac".

Count VI
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, pursuant to Iowa Code sections 147.55(3) and 155A.12(2), and 657 IAC 36.1(4) "c".

D. FACTUAL CIRCUMSTANCES

1. Respondent was issued Iowa pharmacist license number 19740, which is currently active and expires on June 30, 2016.
2. At all relevant times, Respondent was employed as the pharmacist-in-charge at Central Community Hospital in Elkader, Iowa.
3. Expired controlled substances were stored in a locked desk drawer. The drawer contained open and empty bottles of expired controlled substances, sleeves associated with carpulets, and rubber stoppers used on morphine PCAs.
4. Controlled substances listed as expired on perpetual inventories were not found in the locked desk drawer. Several expired controlled substances were unaccounted for, including fentanyl, morphine, chlorthalidone, methylphenidate, diazepam, lorazepam, promethazine with codeine.
5. Documentation of expired controlled substances returned through a reverse distributor showed the following: 16 tablets of methylphenidate hydrochloride were returned when the perpetual inventory showed 68 expired tablets and 0 morphine PCAs were returned when the perpetual inventory showed 4 expired PCAs.

6. Periodic counts of controlled substances contained mathematical errors and entries that were difficult to read. Some controlled substances listed on counts as being entered into a Pyxis station could not be reconciled with the entries into the particular Pyxis station. Several controlled substances were unaccounted for, including APAP/codeine, OxyContin, morphine sulfate ER, oxycodone, hydrocodone/APAP.

7. The perpetual inventory for Schedule II controlled substances had a 3 month gap in records. The page for morphine injection was torn out of the perpetual inventory book and found in a desk drawer.

8. An audit of a seven-month time period in 2013 revealed approximately 600 tablets of hydrocodone/APAP 7.5/325 and 200 tablets of hydrocodone/APAP 5/325 that were unaccounted for.

9. Empty blister packs of hydrocodone/APAP 5/325, hydrocodone/APAP 7.5/325 and Tramadol were found in the pharmacy.

10. In May, 2014, Respondent was terminated from employment at Central Community Hospital as a result of the deficiencies described above.

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 26th day of August, 2014, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



JAMES MILLER, Vice-Chairperson
Iowa Board of Pharmacy
400 SW Eight Street, Suite E
Des Moines, Iowa 50309-4688

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319

Dave Brown
Hansen, McClintock & Riley
Fifth Floor – US Bank Building
520 Walnut Street
Des Moines, IA 50309

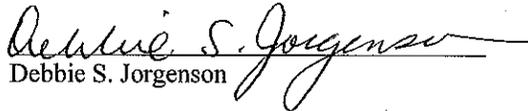
PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

<input type="checkbox"/>	personal service	<input checked="" type="checkbox"/>	first class mail
<input checked="" type="checkbox"/>	certified mail, return receipt requested	<input type="checkbox"/>	facsimile
	Article Number 9171999991703239255400	<input type="checkbox"/>	other _____

on the 27th day of August, 2014.

I declare that the statements above are true to the best of my information, knowledge and belief.


Debbie S. Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	CASE NO. 2014-57
Pharmacist License of)	
)	SETTLEMENT AGREEMENT
MARY MCMILLAN)	AND FINAL ORDER
License No. 19740)	
Respondent.)	

Pursuant to Iowa Code sections 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy ("Board") and Mary McMillan ("Respondent") enter into the following Settlement Agreement and Final Order ("Order") to settle a contested case pending before the Board.

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

1. Respondent's license #19740 is currently active and expires on June 30, 2016.
2. The Board has jurisdiction over the parties and the subject matter of these proceedings.
3. A Statement of Charges was filed against Respondent on August 26, 2014.
4. Respondent admits the allegations contained in the Statement of Charges and acknowledges that the allegations, 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 Settlement Agreement. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
6. Respondent is freely and voluntarily entering into this Order.
7. Respondent acknowledges that she has the right to be represented by counsel on this matter.
8. 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.
9. This Order is subject to approval by a majority of the full Board. If the Board fails to approve this Order, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Order, it shall be the full and final resolution of this matter.

10. This Order shall be part of the permanent record of Respondent 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.
11. Respondent acknowledges and understands that this Order will be reported to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and National Practitioner Databank, as applicable.
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 shall be **INDEFINITELY SUSPENDED**. Respondent shall not be permitted to apply for reinstatement of her pharmacist license until all of the following conditions have been satisfied:
 - a. A minimum of six months has passed from the date of the Board's approval of this Agreement.
 - b. Respondent obtains a complete mental health and substance abuse evaluation from a treatment provider pre-approved by the Board. It is Respondent's responsibility to seek prior approval of the evaluator, ensure the Board is notified at least five days prior to the evaluation, and ensure that the Board's disciplinary file, including Board orders and investigative reports, are provided to the evaluator prior to the evaluation. Failure to comply with any of these requirements automatically renders the evaluation noncompliant. Respondent will not be permitted to seek reinstatement based upon a noncompliant evaluation.
 - c. Respondent delivers to the Board a current, comprehensive, and fully documented mental health and substance abuse evaluation of Respondent performed in accordance with the preceding paragraph "b". The evaluation must conclude that Respondent is fit to practice pharmacy. Any conclusion that Respondent is fit to return to the practice of pharmacy must include an assessment of Respondent's ability to cope with the presence of controlled substances in the pharmacy setting. The evaluation must include any recommendations for treatment.
 - d. Respondent permits the Board to have complete access to Respondent's medical records, including records of substance abuse treatment, as necessary to fully evaluate Respondent's reinstatement request.
15. At such time as Respondent satisfies all of the requirements set forth in paragraph 14, Respondent may petition the Board for reinstatement of Respondent's license and commencement of a period of probation. Reinstatement of Respondent's license shall be at the discretion of the Board.

16. In the event the Board determines that Respondent's license should be reinstated, Respondent's license to practice pharmacy shall be placed on **PROBATION** for a period of five (5) years. The terms of probation include the following:

- a. Respondent must be employed as a pharmacist for a minimum of forty (40) hours per month for at least thirty (30) months of the probationary term. If Respondent cannot satisfy this requirement, the probationary period will extend beyond five (5) years until such time as Respondent can satisfy this requirement.
- b. Respondent shall not possess or use any controlled substance or prescription drug in any form unless the controlled substance or prescription drug has been authorized and prescribed for Respondent by a licensed treating physician or other qualified health care provider. Respondent shall inform all treating physicians and other health care providers of her medical history, including all history of chemical dependency. Respondent shall provide the Board a copy of this notification upon request.
- c. Respondent shall provide witnessed blood, hair, or urine specimens on demand by the Board or its agents. Respondent shall provide such witnessed blood, hair, or urine specimens within the timeframe specified on the day of notice from the Board or the Board's chemical screening program requesting that Respondent provide a specimen. The specimens shall be used for alcohol and drug screening to verify Respondent's compliance with this Agreement. All costs related to the analysis of such specimens shall be paid by Respondent.
- d. To facilitate the preceding paragraph "c", Respondent shall participate in the Board's chemical screening program. Respondent shall complete enrollment in the Board's chemical screening program within thirty (30) days of the date his license is placed on probation. Respondent agrees to comply with all requirements of the chemical screening program and shall be responsible for all costs associated with the program. Respondent consents to disclosure to the Board, by the chemical screening program, of all medical information, including test results, generated by Respondent's contact with the chemical screening program.
- e. Respondent must comply with all treatment recommendations in the evaluation described in paragraph 14"c". Respondent's treatment providers shall submit quarterly reports to the Board documenting Respondent's compliance with treatment for the duration of the treatment. Said quarterly reports are due on March 1, June 1, September 1, and December 1 of each calendar year Respondent is undergoing treatment. Treatment providers shall indicate in the report if treatment is completed and indicate that no further quarterly reports will be submitted as a result.
- f. Respondent permits the Board to have complete access to Respondent's medical records, including records of substance abuse treatment, as necessary to fully evaluate Respondent's compliance with probationary terms.

- g. Respondent shall participate in the Iowa Recovery Network (IPRN) program under the direct support of a pharmacist advocate. Respondent shall comply with all requirements of the IPRN program.
- h. Respondent shall not serve as a pharmacist-in-charge while on probation. Respondent shall not supervise any registered pharmacist-interns or perform any duties of a pharmacy preceptor while on probation.
- i. Respondent shall notify all employers and prospective employers (no later than at the time of an employment interview), including any pharmacist-in-charge, of the resolution of this case and the terms imposed on Respondent by this Agreement. Within fifteen (15) days of undertaking new employment as a pharmacist, Respondent shall cause her pharmacy employer/s, and any pharmacist-in-charge she works under, to send to the Board a written acknowledgment that the employer and pharmacist-in-charge have read this document and understand the terms.
- j. Respondent shall appear before the Board upon request, for the purpose of reviewing her performance as a pharmacist during Respondent's probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
- k. Respondent shall inform the Board, in writing, of any change of home address, telephone number, or place of employment within ten (10) days of such a change.
- l. Respondent shall obey all federal and state laws, rules, and regulations related to the practice of pharmacy.
- m. Respondent understands the Board may impose other terms as a condition of reinstatement Respondent's license.
- n. Respondent shall submit written quarterly reports to the Board, said reports being due on March 1, June 1, September 1, and December 1 during each calendar year of the probationary period. Each quarterly report shall include Respondent's place of employment, current address, Respondent's most recent efforts to implement the provisions of this Agreement (by date), and any further information requested by the Board.

17. Should Respondent violate the terms of this Agreement, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2013) and 657 Iowa Administrative Code chapter 36.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the ___ day of _____, 2015.

MARY MCMILLAN

MARY MCMILLAN
Respondent

This Settlement Agreement and Final Order is accepted by the Iowa Board of Pharmacy on the
10th day of March, 2015.



EDWARD MAIER, Chairperson
Iowa Board of Pharmacy

cc: Laura Steffensmeier
Assistant Attorney General
Hoover Building, 2nd Floor
Des Moines, IA 50319
ATTORNEY FOR THE STATE

David L. Brown
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520 Walnut Street
Des Moines, IA 50309-4119
ATTORNEY FOR RESPONDENT

MARY MCMILLAN


3/02/15