MINUTES OF THE APRIL 3-4, 2017
MEETING OF THE STATE OF OHIO BOARD OF PHARMACY

Monday, April 3, 2017

10:00 a.m. The Ohio State Board of Pharmacy convened in the Kresge Auditorium, of the Medical Sciences Building at the University of Cincinnati, 231 Albert Sabin Way, Cincinnati, Ohio, with the following members present:

Michael A. Moné, RPh, President; Joshua M. Cox, RPh; Megan E. Marchal, RPh; Jennifer M. Rudell, RPh; Fred M. Weaver, RPh; Shawn C. Wilt, RPh; and Kilee S. Yarosh, RPh.

Also present were Steven Schierholt, Executive Director; Nicole Dehner, Chief Legal Counsel; Cameron McNamee, Director of Policy and Communications; and Steven Kochheiser, Assistant Attorney General.

The Board Members introduced themselves to the University of Cincinnati a.m. students.

10:09 a.m. Mr. McNamee presented the Legislative Update.

R-2017-295 Mr. Wilt moved that the Board adopt the following Resolution:

Transfer or Sale of Naloxone by Ohio Law Enforcement Agencies

Pursuant to section 4729.25 of the Revised Code, the Board finds that it is in the public interest to permit the transfer or sale of naloxone (Narcan®) between law enforcement agencies.

The motion was seconded by Mr. Passafume and approved by the Board: Aye-7.

R-2017-296 Mr. Passafume moved that the Board adopt the following Resolution:

Recognition of Additional Basic Life Support Training for Immunization Administration (ORC 4729.41) & Administration of Other Injectable Drugs (ORC 4729.45)

The Board hereby recognizes that CPR/AED or Basic Life Support certification provided by American Safety and Health Institute (ASHI) meets the basic-life support training requirements pursuant to sections 4729.41 and 4729.45 of the Revised Code.

The motion was seconded by Ms. Marchal and approved by the Board: Aye-7.

R-2017-297 Mr. Passafume moved that the Board adopt the following Resolution:
**Extension for Licensure of Entities Possessing Controlled Substances**

The Board hereby grants an extension to all previously exempted prescribers that possess controlled substances in their offices from the requirement to obtain a terminal distributor of dangerous drugs license in accordance with section 4729.541 of the Revised Code. This extension is hereby valid until June 1, 2017.

The motion was seconded by Ms. Yarosh and approved by the Board: Aye-7.

**R-2017-298**

Mr. Wilt moved that the Board adopt the following Resolution:

**Shipping into Ohio for Sole Purpose of Drug Destruction**

The Board hereby acknowledges that the shipment of dangerous drugs to an Ohio licensed reverse distributor for the sole purpose of destruction or wasting of the drugs does not constitute a sale as defined by Ohio Revised Code and therefore does not require the entity shipping the dangerous drugs to possess an Ohio license.

The motion was seconded by Ms. Rudell and approved by the Board: Aye-7.

**10:33 a.m.**

Mr. McNamee presented a Rules packet to the Board for approval to file with CSI and JCARR.

**R-2017-299**

Mr. Weaver moved that Rules 4729-5-30, 4729-37-05, and 4729-37-04 be approved for filing as amended with CSI and JCARR. The motion was seconded by Mr. Passafume and approved by the Board: Aye-7.

**11:21 a.m.**

The Board recessed briefly.

**11:30 a.m.**

The meeting reconvened in the Kresge Auditorium.

The Board was joined by Assistant Attorney General Steven Kochheiser to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of Emily Eppley, Coshocton, Ohio.

**11:46 a.m.**

The hearing ended and the record was closed.

Ms. Marchal moved that the Board recess in order to consider the quasi-judicial matter in accordance with Chapter 119. of the Revised Code and the case precedent of Angerman v. State Medical Bd. (1990) 70 Ohio App.3d 346 and TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al. (1998) 81 Ohio St.3d 58. The motion was seconded by Ms. Rudell and a roll-call vote was conducted by President Moné as follows: Cox-yes; Marchal-yes; Passafume-yes; Rudell-yes; Weaver-yes; Wilt-yes and Yarosh-yes.

**12:04 p.m.**

The recess ended and the hearing was opened to the public.

**R-2017-300**

After votes were taken in public session, the Board adopted the following order in the matter of Emily Eppley, Coshocton, Ohio.
ORDER OF THE STATE BOARD OF PHARMACY
(Case Number 2016-1555)

In The Matter Of:

Emily Eppley
31619 State Route 83
Coshocton, Ohio 43812
(License No. 03-2-36596)

INTRODUCTION


Emily Eppley was not present nor represented by Counsel. The State of Ohio was represented by Steven Kochheiser, Assistant Attorney General.

SUMMARY OF EVIDENCE

State’s Witnesses:
1. Jason Doty—State of Ohio Board of Pharmacy

Respondent’s Witnesses:
None

State’s Exhibits:
1. Notice of Opportunity for Hearing 12-01-2016
2. Credential View Screen 03-10-2017
3. Application 06-05-2016
4. Statement of Emily Eppley 05-19-2016
5. Police Report 04-03-2016
6. Certified Court Records 04-03-2016

Respondent’s Exhibits:
None

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, considered the evidence, and weighed the credibility of each, the Board finds the following to be fact:

1. On Emily Eppley’s application, she truthfully answered “YES” to question 6 that inquired whether she had ever been charged or convicted of a felony or a misdemeanor other than a minor traffic violation (even if expunged or sealed). She included a statement with her application that detailed her arrest and subsequent misdemeanor conviction related to the consumption of alcohol.
On or about April 3, 2016, Emily Eppley was charged by the Ohio State Highway Patrol in Zanesville, Ohio with Operating a vehicle under the influence of alcohol and/or a drug of abuse and Operating a Vehicle Under the Influence Per Se, High Breath Levels. After she was pulled over for driving the wrong way on a highway, she submitted a breath sample of .214 BAC, a high test, over the legal limit of .08. On or about June 17, 2016, in exchange for the dismissal of the other charges, she plead no contest to Operating a Vehicle Under the Influence Per Se, High Breath Levels, a first degree misdemeanor. She was sentenced to complete the 72-hour driver intervention program (DIP), 10 days in jail, 30 days SCRAM, and required to pay costs and a $750 fine. Case Number TRC 1602166.

CONCLUSIONS OF LAW

1. Such conduct as set forth in paragraphs (1)(a) of the Findings of Fact constitutes a violation of each of the following Sections of the ORC:

   a. Guilty of gross immorality, ORC Section 4729.16(A)(1); and/or

   b. Guilty of willfully violating, any of the provisions of this chapter, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925. or 3719. of the Revised Code, or any rule adopted by the board under those provisions; ORC Section 4729.16(A)(5).

2. Such conduct as set forth in paragraph (1)(a) of the Findings of Fact constitutes a violation of Rule 4729-5-04(C) of the OAC, not of good habits.

DECISION OF THE BOARD

On the basis of the Finding of Fact set forth above, and after consideration of the record as a whole, the State of Ohio Board of Pharmacy hereby places the pharmacist identification card, No 03-2-36596, held by Emily Eppley on probation for a period of five years beginning on the effective date of this Order, with the following conditions:

1. Emily Eppley must enter into and adhere to the terms of a new contract, signed within thirty days after the effective date of this Order, with an Ohio Department of Mental Health and Addiction Services (ODMHAS) treatment provider or a treatment provider acceptable to the Board for a period of not less than five years and, upon signing, submit a copy of the contract to the Board office. Failure to adhere to the terms of the treatment contract will be considered a violation of the Board’s Order and subject Emily Eppley to potential sanctions up to and including revocation of license. The contract must provide that:

   a. Random, observed urine drug screens shall be conducted at least once each month.

   b. The urine sample must be given within twelve hours of notification. The urine drug screen must include testing for creatinine or specific gravity of the sample as the dilutional standard.

   c. Alcohol and Ethyl Glucoronide (ETG) must be added to the standard urine drug screen.
d. Results of all drug screens must be negative. Refusal of a drug screen or a diluted drug screen is equivalent to a positive result. Any positive results, including those which may have resulted from ingestion of food, but excluding false positives which resulted from medication legitimately prescribed, indicates a violation of the contract.

e. In the event of a negative diluted screen, a hair sample test must be completed at the cost of the Emily Eppley in a timeframe consistent with the drug lab’s recommended policy, but in any event no later than 12 days after the negative diluted screen.

2. The intervener/sponsor shall submit reports to the Board, in a format acceptable to the Board, indicating drug screens and their results in a timely fashion. Actual copies of drug screens shall be made available to the Board upon request.
   a. Attendance is required a minimum of three times per calendar week (Sunday through Saturday) on separate days, at an Alcoholics Anonymous, Narcotics Anonymous, and/or similar support group meeting.

b. The program shall immediately report to the Board any violations of the contract and/or lack of cooperation.

3. Emily Eppley shall not refuse an employer provided drug or alcohol screen. If the Board becomes aware of any positive drug or alcohol screen results that were obtained in the course of employment or any mechanism other than via the signed contract with ODMHAS, the Board shall treat these results as a violation of the Board’s Order and request Emily Eppley reappear before the Board for possible additional sanctions, including and up to revocation of license.

4. Emily Eppley shall not refuse a breathalyzer or other drug testing requested by law enforcement during the duration of probation. The Board shall treat any such refusal as a violation of the Board’s Order and request Emily Eppley reappear before the Board for possible additional sanctions, including and up to revocation of license.

5. Emily Eppley must submit quarterly progress reports to the Board (due January 10, April 10, July 10, and October 10 of each year of probation) that include:

   a. The written report and documentation provided by the treatment program pursuant to the contract, and

   b. A written description of Emily Eppley’s progress towards recovery and what Emily Eppley has been doing during the previous three months.

6. Other terms of probation are as follows:

   a. Pursuant to Section 4729.16 of the Ohio Revised Code, the State of Ohio Board of Pharmacy imposes a monetary penalty in the amount of $800.00, by means of a cashier’s check made payable to “Treasurer, State of Ohio,” mailed with the enclosed form to the OSBP, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Order.
b. Emily Eppley must submit to the Board copies of her substance abuse evaluations completed as a condition of her court program and any evaluations completed as part of her involvement with an approved monitoring program. If no substance abuse evaluation has been completed, Emily Eppley must complete one and submit the results to the Board. All documentation should be provided to the Board immediately upon receipt of this Order.

c. Emily Eppley must meet at least annually with the Board’s Probation Committee, the first meeting to be held May 3, 2017. At such time, the Probation Committee may reduce the length of probation or the number of annual meetings required if Emily Eppley is deemed to be in compliance and has the ability to engage in the practice of pharmacy with reasonable skill, care, and competence.

d. The State of Ohio Board of Pharmacy hereby declares that Emily Eppley’s pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.

e. Emily Eppley may not serve as a responsible pharmacist.

f. Emily Eppley may not destroy, assist in, or witness the destruction of controlled substances.

g. Emily Eppley may not work in a pharmacy more than 40 hours per week or 80 hours over a two week period.

h. Emily Eppley must, during the first six months of practice, work only with a pharmacist whose license is in good standing.

i. Emily Eppley must not violate the drug laws of Ohio, any other state, or the federal government.

j. Emily Eppley must abide by the rules of the State of Ohio Board of Pharmacy.

k. Emily Eppley must comply with the terms of this Order.

l. Emily Eppley’s license is deemed not in good standing until successful completion of the probationary period.

7. Emily Eppley must immediately report any violation of the terms of this probation to the Board by contacting legal@pharmacy.ohio.gov. Failure to self-report any violation shall be treated as a violation of this Board’s Order and will subject Emily Eppley to possible additional sanctions, including and up to revocation of license.
8. Any violation of probation or this Board’s Order may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code, including and up to revocation of Emily Eppley’s license.

At the conclusion of the probationary period, the Board will issue a notice of opportunity for hearing to Emily Eppley regarding the status of Emily Eppley’s probation and whether Emily Eppley has successfully met all terms of probation and may be considered in good standing.

Ms. Marchal moved for Findings of Fact; Mr. Weaver seconded the motion. Motion passed (Aye-7/Nay-0).

Mr. Cox moved for Conclusions of Law; Mr. Passafume seconded the motion. Motion passed (Aye-/Nay-0).

Ms. Yarosh moved for Action of the Board; Mr. Wilt seconded the motion. Motion passed (Aye-7/Nay-0).

SO ORDERED.

12:08 p.m. The Board recessed for lunch.

12:59 p.m. The meeting reconvened in the Kresge Auditorium.

The Board was joined by Assistant Attorney General Steven Kochheiser to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of Charles Nuhfer, Columbus, Ohio.

1:19 p.m. The hearing ended and the record was closed.

Ms. Marchal moved that the Board recess in order to consider the quasi-judicial matter in accordance with Chapter 119. of the Revised Code and the case precedent of Angerman v. State Medical Bd. (1990) 70 Ohio App.3d 346 and TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al. (1998) 81 Ohio St.3d 58. The motion was seconded by Ms. Rudell and a roll-call vote was conducted by President Moné as follows: Cox-yes; Marchal-yes; Passafume-yes; Rudell-yes; Weaver-yes; Wilt-yes and Yarosh-yes.

1:29 p.m. The recess ended and the hearing was opened to the public.

R-2017-301 After votes were taken in public session, the Board adopted the following order in the matter of Charles Nuhfer, Columbus, Ohio.
(Case Number 2015-1835)

In The Matter Of:

Charles Nuhfer, RPh
728 Kerr Street
Columbus, Ohio 43215
(License No. 03-3-23640)

INTRODUCTION


Charles Nuhfer was not present nor represented by Counsel. The State of Ohio was represented by Steven Kochheiser, Assistant Attorney General.

SUMMARY OF EVIDENCE

State’s Witnesses:
1. John West—State of Ohio Board of Pharmacy

Respondent’s Witnesses:
None

State's Exhibits:
1. Notice of Opportunity for Hearing(s) 02-05-2016 & 10-24-2016
2. Credential View Screen 03-10-2017
3. Confidential Patient Key No Date
4. Indictment 04-15-2016
6A. Statement of Charles Nuhfer 10-12-2015
6B. Statement of Charles Nuhfer 12-21-2015
6C. Statement of Charles Nuhfer 12-21-2015
7. Statement of Dr. William Mains, MD 01-05-2016
8. Prescription Records Various
9. Prescription Records Various

Respondent's Exhibits:
None

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the Board finds the following to be fact:
1. The Board received a complaint about questionable dispensing taking place at CVS Pharmacy at 9151 South Old State Road Lewis Center, Ohio 43055.

2. While conducting an investigation on the questionable dispensing, Charles Nuhfer was interviewed by an Agent of the Board and admitted to filling false prescriptions with knowledge that the prescriptions were false.

a. On or about September 13, 2015, he knowingly made a false statement in a report or record required by Chapter 3719. or 4729. of the Revised Code when he filled a fraudulent prescription for patient S.S. under prescription number, CVS #0888118, without authorization from Dr. William Mains, for one hundred and eighty (180) tablets of hydrocodone 10/325mg, a Schedule II controlled substance.

b. On or about November 9, 2015, he knowingly made a false statement in a report or record required by Chapter 3719. or 4729. of the Revised Code when he filled a fraudulent prescription for patient S.S. under prescription number, CVS #0900445, without authorization for Dr. William Mains, for one hundred and eighty (180) tablets of hydrocodone 10/325mg, a Schedule II controlled substance.

c. On or about November 22, 2015, he knowingly made a false statement in a report or record required by Chapter 3719. or 4729. of the Revised Code when he filled a fraudulent prescription for patient S.S. under prescription number, CVS #0903788, without authorization from Dr. William Mains, for one hundred and eighty (180) tablets of hydrocodone 10/325mg, a Schedule II controlled substance.

d. On or about December 5, 2015, he knowingly made a false statement in a report or record required by Chapter 3719. or 4729. of the Revised Code when he filled a fraudulent prescription for patient S.S. under prescription number, CVS #0906713, without authorization from Dr. William Mains, for one hundred and eighty (180) tablets of hydrocodone 10/325mg, a Schedule II controlled substance.

e. On or about December 15, 2015, he knowingly made a false statement in a report or record required by Chapter 3719. or 4729. of the Revised Code when he filled a fraudulent prescription for patient S.S. under prescription number, CVS #0909237, without authorization from Dr. William Mains, for one hundred and eighty (180) tablets of hydrocodone 10/325mg, a Schedule II controlled substance.

3. On or about April 15, 2016, Charles Nuhfer was indicted in Delaware County Court of Common Pleas on five counts of illegal processing, a fourth degree felony. On or about October 17, 2016, he entered a plea of guilty to three counts of illegal processing. As a result of the guilty plea and agreement of all parties to the case, the court granted Intervention in lieu of conviction. He is currently under the jurisdiction of the Delaware County Adult Court Services for a period not to exceed 18 months from October 17, 2016, and must fulfill several terms and conditions. Case No. 2016 CR-I-04-0189.

4. In addition, the Board is in receipt of information that Charles Nuhfer filled six (6) prescriptions prior to the order date authorized by Dr. Williams Mains, causing duplicate therapy for patient S.S.
a. On or about June 15, 2015, he filled a prescription for patient S.S. under prescription number, CVS #870211, for one hundred and eighty (180) hydrocodone-acetaminophen 10/325mg, which had an order start date of June 20, 2015.

b. On or about July 23, 2015, he filled a prescription for patient S.S. under prescription number, CVS #877552, for one hundred and eighty (180) hydrocodone-acetaminophen 10/325mg, which had an order start date of August 13, 2015.

c. On or about August 14, 2015, he filled a prescription for patient S.S. under prescription number, CVS #882289, for one hundred and eighty (180) hydrocodone-acetaminophen 10/325mg, which had an order start date of September 13, 2015.

d. On or about September 22, 2015, he filled a prescription for patient S.S. under prescription number, CVS #890155, for one hundred and eighty (180) hydrocodone-acetaminophen 10/325mg, which had an order start date of October 13, 2015.

e. On or about October 11, 2015, he filled a prescription for patient S.S. under prescription number, CVS #894092, for one hundred and eighty (180) hydrocodone-acetaminophen 10/325mg, which had an order start date of November 13, 2015.

f. On or about October 23, 2015, he filled a prescription for patient S.S. under prescription number, CVS #896940, for one hundred and eighty (180) hydrocodone-acetaminophen 10/325mg, which had an order start date of December 13, 2015.

CONCLUSIONS OF LAW

1. Such conduct as set forth in paragraphs (2)(a) through (2)(e), (3), and (4)(a) through (f) of the Findings of Fact each constitutes illegal processing of drug documents in violation of Section 2925.23 of the Ohio Revised Code (ORC), each violation being a felony of the fourth degree.

2. Such conduct as set forth in paragraph (2), (2)(a) through (2)(e), (3), and (4)(a) through (f) of the Findings of Fact constitutes the following violations of the ORC:

   a. Guilty of a felony or gross immorality, ORC Section 4729.16(A)(1); and

   b. Guilty of dishonesty or unprofessional conduct in the practice of pharmacy, ORC Section 4729.16(A)(2); and

   c. Guilty of willfully violating...any provisions of chapter 4729., Chapter 2925. or 3719, or any rule adopted by the board under those provisions, ORC Section 4729.16(A)(5).

3. Such conduct as set forth in paragraphs (4), (4)(a) through 4(f) of the Findings of Fact each constitutes a violation of each of the following sections of Chapter 4729-5 of the Ohio Administrative Code (OAC):

   a. Failure to conduct proper drug utilization review, OAC Rule 4729-5-20; and

   b. Improper processing of a prescription, OAC Rule 4729-5-21; and

4. Finally, such conduct as set forth in paragraph (2), (2)(a) through (2)(e), (3), and (4)(a) through (f) of the Findings of Fact constitutes a violation of 4729-5-04(C) of the OAC.

DECISION OF THE BOARD

1. Pursuant to Section 4729.16 of the Ohio Revised Code, and pursuant to Section 4729-9-01(E) of the Ohio Administrative Code, and after consideration of the record as a whole, the State of Ohio Board of Pharmacy adjudicates the matter of Charles Nuhfer as follows:

On the basis of the Findings of Fact and section (1) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Pharmacist license, No. 03-3-23640, held by Charles Nuhfer effective as of the date of the mailing of this Order.

On the basis of the Findings of Fact and section (2) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Pharmacist license, No. 03-3-23640, held by Charles Nuhfer effective as of the date of the mailing of this Order.

On the basis of the Findings of Fact and section (3) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Pharmacist license, No. 03-3-23640, held by Charles Nuhfer effective as of the date of the mailing of this Order.

On the basis of the Findings of Fact and section (4) of the Conclusions of Law, the State of Ohio Board of Pharmacy hereby revokes permanently the Pharmacist license, No. 03-3-23640, held by Charles Nuhfer effective as of the date of the mailing of this Order.

2. Charles Nuhfer, pursuant to Section 4729.16(B) of the Ohio Revised Code, must return his identification card and license (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Order unless the Board office is already in possession of both. The identification card and wall certificate should be sent by certified mail, return receipt requested.

3. Pursuant to Section 4729.16 of the Ohio Revised Code, the State of Ohio Board of Pharmacy imposes a monetary penalty in the amount of $5,000.00, by means of a cashier’s check made payable to “Treasurer, State of Ohio,” mailed with the enclosed form to the OSBP, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Order.

Mr. Passafume moved for Findings of Fact; Ms. Marchal seconded the motion. Motion passed (Aye-7/Nay-0).

Mr. Weaver moved for Conclusions of Law; Ms. Yarosh seconded the motion. Motion passed (Aye-7/Nay-0).

Mr. Wilt moved for Action of the Board; Ms. Yarosh seconded the motion. Motion passed (Aye-7/Nay-0).
The Board Members introduced themselves to the University of Cincinnati p.m. students.

Mr. McNamee presented a Rules packet to the Board for approval to file with JCARR.

Ms. Yarosh moved that the Board strike ‘Ohio’ from Rule 4729-3-01. The motion was seconded by Ms. Marchal and approved by the Board: Aye-7.

Mr. Weaver moved that Rule 4729-3-01 be approved as amended for filing with JCARR. The motion was seconded by Ms. Rudell and approved by the Board: Aye-7.

Mr. Passafume moved that Rule 4729-5-14 be approved for filing with JCARR. The motion was seconded by Mr. Cox and approved by the Board: Aye-7.

The Board was joined by Assistant Attorney General Steven Kochheiser to create a record in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of Kristen Shirkey, Fairfield, Ohio.

The hearing ended and the record was closed.

Ms. Marchal moved that the Board recess in order to consider the quasi-judicial matter in accordance with Chapter 119. of the Revised Code and the case precedent of Angerman v. State Medical Bd. (1990) 70 Ohio App.3d 346 and TBC Westlake Inc. v. Hamilton Cty Bd of Revision, et al. (1998) 81 Ohio St.3d 58. The motion was seconded by Mr. Passafume and a roll-call vote was conducted by President Moné as follows: Cox-yes; Marchal-yes; Passafume-yes; Rudell-yes; Weaver-yes; Wilt-yes and Yarosh-yes.

The recess ended and the hearing was opened to the public.

After votes were taken in public session, the Board adopted the following order in the matter of Kristen Shirkey, Fairfield, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY
(Case Number 2014-2075-B)

In The Matter Of:

Kristen Shirkey, RPh
4 Jupiter Court
Fairfield, Ohio 45014
(License No. 03-1-20682)

INTRODUCTION

The Matter of Kristen Shirkey came for consideration on April 3, 2017, before the following members of the State of Ohio Board of Pharmacy (Board): Michael A. Moné, R.Ph., Presiding;

Kristen Shirkey was not present nor represented by Counsel. The State of Ohio was represented by Steven Kochheiser, Assistant Attorney General.

SUMMARY OF EVIDENCE

State’s Witnesses:
1. Richard Haun—State of Ohio Board of Pharmacy

Respondent’s Witnesses:
None

State’s Exhibits:
1. Notice of Opportunity for Hearing 04-12-2016
2. Credential View Screen 03-10-2017
5. Statement of Todd Roller, Kroger #909 Responsible Person No Date
6. Patient SS Profile 03-17-2015
7. Patient CV Profile 03-17-2015
8. Oxycodone Perpetual Inventory 11-19-2014
9. CV Prescription Records 09-10-2014

Respondent’s Exhibits:
None

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, considered the evidence, and weighed the credibility of each, the Board finds the following to be fact:

1. During a Board investigation related to an error in dispensing at Kroger Pharmacy #909, 1474 Main Street, Hamilton, Ohio, where Kristen Shirkey was employed, it was discovered that on or about September 8, 2014, a prescription was received for patient S.S. for 60 tablets of Oxycontin 80 mg. On or about September 10, 2014 a prescription was received for 16 tablets of Percocet 5/325 for patient C.V. The two prescriptions were correctly filled and given to Kristen Shirkey for labeling and final verification. She correctly labeled the prescriptions; however, she failed to properly complete final association of the prescription with the patient’s bag and dispensed the 60 tablets of Oxycontin 80 mg to patient C.V. instead of the prescribed 16 tablets of Percocet 5/325. Kristen Shirkey failed to match up the correct receipts with the correct medication.

a. During an interview with an Agent of the Board, Kristen Shirkey admitted that she failed to match up the correct receipts with the correction medication. She confirmed that the receipt for patient C.V. under prescription number 2340878 was placed with the prescription for S.S.
2. The medication dispensed in error was returned to Kroger Pharmacy #909, 1474 Main Street Hamilton, OH 45013. While counting the returned prescription, Kristen Shirkey determined that 10 oxycodone 80mg tablets were missing. She failed to report this loss to the Board and returned the previously dispensed tablets back to the stock bottle for use rather than seclude them from destruction. During her interview with the Board’s Compliance Specialist, she confirmed that she counted the returned tablets and that those tablets “were somehow put back into the stock bottle.”

CONCLUSIONS OF LAW

1. Similarly, such conduct as set forth in paragraphs (1) and (1)(a) of the Findings of Fact also constitutes a violation of Section 3715.64(A)(10)(d) of the ORC.

2. Additionally, such conduct as set forth in paragraphs (1) and (2) of the Findings of Fact each also constitutes a violation of each of the following Sections of the ORC:
   a. Being guilty of unprofessional conduct in the practice of pharmacy, ORC Section 4729.16(A)(2); and/or
   b. Being guilty of willfully violating, any of the provisions of this chapter, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925. or 3719. of the Revised Code, or any rule adopted by the board under those provision; ORC Section 4729.16(A)(5).

3. Such conduct as set forth in paragraph (2) of the Allegations section, if proven, also constitutes a violation of Rule 4729-9-04(A) of the OAC.

DECISION OF THE BOARD

1. Pursuant to Section 4729.16 of the Ohio Revised Code, the State of Ohio Board of Pharmacy imposes a monetary penalty in the amount of $1,350.00, by means of a cashier’s check made payable to “Treasurer, State of Ohio,” mailed with the enclosed form to the OSBP, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Order.

2. Kristen Shirkey must obtain, within 90 days from the effective date of this Agreement, 3 hours of approved continuing pharmacy education (0.3 CEUs) in medication errors and/or patient safety, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

3. Kristen Shirkey must obtain, within 90 days from the effective date of this Agreement, 3 hours of approved continuing pharmacy education (0.3 CEUs) in law, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

Mr. Passafume moved for Findings of Fact; Ms. Marchal seconded the motion. Motion passed (Aye-7/Nay-0).

Ms. Yarosh moved for Conclusions of Law; Mr. Cox seconded the motion. Motion passed (Aye-7/Nay-0).
Mr. Wilt moved for Action of the Board; Mr. Passafume seconded the motion. Motion passed (Aye-7/Nay-0).

SO ORDERED.

2:56 p.m. The Board conducted a Q&A session with the students of the University of Cincinnati.

3:14 p.m. The Board recessed for the day.

Tuesday, April 4, 2017

9:00 a.m. The Ohio State Board of Pharmacy convened in Room South B&C, 31st Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Michael A. Moné, RPh, President; Joshua M. Cox, RPh; Megan E. Marchal, RPh; Curtis L. Passafume, Jr., RPh; Fred M. Weaver, RPh; and Shawn C. Wilt, RPh.

Jennifer M. Rudell, RPh; Absent.

Kilee S. Yarosh, RPh; Absent.

R-2017-306 The Board received an application for the Continuing Education Provider Status of Julia Landis, RPh (03-2-32613) Troy, Ohio. Ms. Marchal moved that the Continuing Education Provider Status be approved. The motion was seconded by Mr. Passafume and approved by the Board: Aye-5.

R-2017-307 Mr. Cox moved that the Board adopt the following Resolution:

A Resolution for Betty J. Jones

WHEREAS, the administrative and investigative efforts of Betty J. Jones, as a Compliance Specialist with the State of Ohio Board of Pharmacy, have directly led to the successful and thoughtful enforcement of the Ohio Drug Laws; and

WHEREAS, these efforts have contributed to the ongoing protection and safety of the citizens of Ohio; therefore

BE IT RESOLVED, that the State of Ohio Board of Pharmacy hereby commends Betty J. Jones for more than 12 years of exemplary service and performance to the Board and to the people of Ohio in carrying out the responsibilities of his position, and

BE IT ALSO RESOLVED, that we, the members of the State of Ohio Board of Pharmacy, in its one hundred thirty-third year, so express our profound appreciation to Betty J. Jones for her dedication and service to the Board and the citizens of Ohio, and

BE IT FURTHER RESOLVED, that this resolution be spread upon the permanent minutes
of the State of Ohio Board of Pharmacy.

The motion was seconded by Mr. Passafume and approved by the Board: Aye-5.

Mr. Schierholtz gave the Executive Director report.

9:10 a.m. Ms. Reed presented the Medical Marijuana Patient and Caregivers Rules to the Board.

Mr. Passafume moved that the Patient and Caregivers Rules be approved for filing with CSI. The motion was seconded by Ms. Marchal and approved by the Board: Aye-5.

9:57 a.m. The Board recessed briefly.

10:07 a.m. The meeting reconvened in Room South B&C.

Mr. Moné announced that the following Settlement Agreement has been signed by all parties and is now effective:

**IN THE MATTER OF:**
**CASE NO. 2016-1476-B**

Bradford James, RPh
5908 Alexa Lane
Sylvania, Ohio 43560
License No. 03-3-17237

**SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY**

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (OSBP) and Bradford James, for the purpose of resolving all issues between the parties relating to the OSBP investigation of the error in dispensing of RX#641194. Together, OSBP and Bradford James are referred to hereinafter as “the parties.”

**JURISDICTION**

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the OSBP has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.16 of the Ohio Revised Code to practice pharmacy as in the state of Ohio.

2. Bradford James is a licensed pharmacist under license number 03-3-17237.

**FACTS**

1. On or about April 27, 2016, the OSBP initiated an investigation of Bradford James, pharmacist license number 03-3-17237, related to Bradford James’s error in dispensing of prescription number 641194.
2. On or about November 23, 2016, the OSBP sent a Notice of Opportunity for Hearing to Bradford James, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Bradford James neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated November 23, 2016; however, the OSBP has evidence sufficient to sustain the allegations and hereby adjudicates the same. Further, the Board finds Violations of Law as set forth in one through three of the Notice; the Board hereby dismisses Violations of Law four and five of the notice letter dated November 23, 2016.

3. Bradford James agrees to pay, as full payment for all charges made against him as referenced in paragraph two above, to the OSBP the amount of $500.00, by means of a cashier’s check made payable to “Treasurer, State of Ohio,” mailed with the enclosed form to the OSBP, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.

4. Bradford James must obtain, within 90 days from the effective date of this Agreement, 6 hours of approved continuing pharmacy education (0.6 CEUs) in medication errors and/or patient safety, which may not also be used for license renewal. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

5. Bradford James agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

6. Bradford James understands that he has the right to be represented by counsel for review and execution of this agreement.

7. Bradford James agrees and acknowledges that this OSBP disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license, including to the OSBP on renewal applications or applications for a new license.

8. Bradford James waives his right to an appeal and an opportunity to be heard pursuant to Chapter 119 of the Ohio Revised Code and specifically withdraws his request for a hearing in this matter.
9. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

10. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

11. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

R-2017-310 Ms. Marchal moved that the Probation Committee Meeting Minutes of March 8, 2017, be approved as written. The motion was seconded by Mr. Weaver and approved by the Board: Aye-5.

R-2017-311 Mr. Weaver moved that the Conference Call Minutes of March 21, 2017, be approved as written. The motion was seconded by Mr. Passafume and approved by the Board: Aye-5.

R-2017-312 Mr. Weaver moved that the Conference Call Minutes of February 24, 2017, be approved as written. The motion was seconded by Mr. Cox and approved by the Board: Aye-5.

R-2017-313 Mr. Passafume moved that the Conference Call Minutes of February 21, 2017, be approved as written. The motion was seconded by Mr. Weaver and approved by the Board: Aye-5.

R-2017-314 Mr. Wilt moved that the Meeting Minutes of March 6-7, 2017, be approved as written. The motion was seconded by Ms. Marchal and approved by the Board: Aye-5.

10:13 a.m. Ms. Dehner led a discussion regarding tolling and presented a draft tolling matrix for licensees on probation.

R-2017-315 Mr. Passafume moved to approve the tolling matrix as amended. The motion was seconded by Mr. Weaver and approved by the Board: Aye-5.

10:31 a.m. The Board discussed the Humana Pharmacy Linear Dispensing Unit V6.

10:40 a.m. Ms. Rudell joined the meeting.

10:54 a.m. The Board recessed briefly.

11:00 a.m. The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Steven Kochheiser to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of Toxicology Associates, Inc., Columbus, Ohio.

12:29 p.m. The Board recessed for lunch.

1:30 p.m. The following candidates for licensure by reciprocity participated in a discussion of pharmacy laws and rules with Ms. Terri Ghittman, OARRS Pharmacist, in Room South A, 31st Floor of the Vern Riffe Center for the Government and the Arts:
**ANDEEP SINGH BAL**
**FLORIDA**

**ANDREW T. BECKER**
**OKLAHOMA**

**ABDUL MUNEEM CHOWDHURY**
**ALABAMA**

**LAURA WILLIAMSON CLARK**
**MISSISSIPPI**

**NASR IBRAHIM NASR ELOKSH**
**MICHIGAN**

**JUDITH ANN GIORDAN**
**WEST VIRGINIA**

**MATTHEW RYAN GROSE**
**WEST VIRGINIA**

**SARAH JANE HUBER**
**NEW YORK**

**ASMA JAFRI**
**MARYLAND**

** DANIEL FREDERICK JENNICHES**
**PENNSYLVANIA**

**HEATHER ANN KAECHER**
**PENNSYLVANIA**

**HANNAH KNIPP**
**KENTUCKY**

**RACHAEL LU**
**MICHIGAN**

**DELLILAH NAVARR**
**KENTUCKY**

**KEVIN ORDONS**
**PENNSYLVANIA**

**DONALD EDWARDS ROBBINS**
**MARYLAND**

**BRIANNA THOMPSON**
**WEST VIRGINIA**

**PAULETTE RHODEN**
**MARYLAND**

**JORDAN MICHELE SMITH**
**KENTUCKY**

**ZACHARY TYLER TACKETT**
**NORTH CAROLINA**

**1:44 p.m.** The meeting reconvened in Room South B&C.

Ms. Marchal moved that the Board go into Executive Session to consider the investigation of charges or complaints against a licensee, confer with Board counsel regarding a pending or imminent court action and to discuss matters required to be confidential by law pursuant to Section 121.22(G)(1), (3) & (5) of the Ohio Revised Code. The motion was seconded by Mr. Passafume and a roll-call vote was conducted by President Moné as follows: Cox-yes; Marchal-yes; Passafume-yes; Rudell-yes; Weaver-yes; and Wilt-yes.

**2:42 p.m.** The meeting reconvened in Room South B&C.

Mr. McNamee presented an amended Resolution for the Definition of Opioid Analgesic

Mr. Passafume moved that the Board adopt the following Resolution:

**Definition of Opioid Analgesic**

For the purposes of enforcing section 4729.46, the Board hereby acknowledges that an opioid analgesic does not include a controlled substance medication utilized as an antidiarrheal.

For the purposes of enforcing section 4729.46, the Board hereby acknowledges that an opioid analgesic does not include medications containing buprenorphine that are used for the treatment of opioid dependence or abuse, as indicated on the product’s labeling.

The motion was seconded by Ms. Marchal and approved by the Board: Aye-6.
2:48 p.m. Mr. McNamee presented Rule 4729-5-40 to the Board for approval to file with JCARR.

R-2017-317 Mr. Passafume moved that Rule 4729-5-40 be approved for filing with JCARR. The motion was seconded by Ms. Marchal and approved by the Board: Aye-6.

2:58 p.m. The Board went back on the record in the matter of Toxicology Associates, Inc.

4:10 p.m. The hearing in the matter of Toxicology Associates, Inc. has been continued until the next available date on the Board’s docket.

The Board recessed briefly.

Mr. Weaver left the meeting.

4:16 p.m. The meeting reconvened in Room South B&C.

Ms. Southard presented the Licensing report.

Mr. Griffin presented the Compliance & Enforcement update.

R-2017-318 The Board received a VPP Inspection extension request of CVS Caremark (02-1524100). Mr. Passafume moved that the Board approved the request. The motion was seconded by Mr. Wilt and approved by the Board: Aye-5.

R-2017-319 Ms. Marchal moved that the Board adopt the following Resolution:

One-Time Extension of State Licensure or VAWD Accreditation Requirement for Virtual Wholesale Distributor and Third Party Logistics Provider Renewal

Pursuant to section 4729-9-28(c) and 4729-9-29(c) of the Ohio Administrative Code, to renew their license, a licensed Virtual Wholesale Distributor or a licensed Third Party Logistics Provider shall possess a current and valid license to distribute dangerous drugs in the state or jurisdiction in which the entity is located. If a state does not license such entities, the facility must maintain verified-accredited wholesale distributors (VAWD) accreditation from the National Association of Boards of Pharmacy (NABP). The Board previously granted a one-time renewal to such entities on April 4, 2016.

Licensed Virtual Wholesale Distributors and Third Party Logistics Providers will be granted an additional one-time renewal, provided they have already submitted their application to NABP for VAWD Accreditation and can show proof thereof, and must demonstrate compliance with the above requirement by June 30, 2018.

During the 2017 Wholesale Distributor renewal period, such entities must provide a copy of their VAWD application and attest that on or before June 30, 2018 they will provide evidence of one of the following to the Board:

- A valid state license to distribute dangerous drugs in the state in which the entity is physically located; or
• A letter from the state licensing agency where the entity is physically located that indicates that the state does not license such entities and VAWD accreditation from the National Association of Boards of Pharmacy.

The motion was seconded by Mr. Passafume and approved by the Board: Aye-5.

4:25 p.m.  Mr. Garner gave the OARRS/IT report.

R-2017-320  Mr. Cox moved that the Board rescind Resolution 2010-013 and adopt the following Resolution as a Board policy:

**Release of De-Identified Data & Statistics From OARRS**

**Policy:** The Board may release de-identified data for research or educational purposes. Database statistics and law enforcement outcomes may be provided in summary, statistical or aggregate form.

**Related laws:**
ORC 4729.80(C): Information contained in the database and any information obtained from it is confidential and is not a public record. Information contained in the records of requests for information from the database is confidential and is not a public record. Information that does not identify a person may be released in summary, statistical, or aggregate form.
OAC 4729-37-10: The board of pharmacy may provide or present database statistics and law enforcement outcomes based on request information pursuant to section 4729.80 of the Revised Code. The information shall not identify a person and will be provided as determined by the board of pharmacy in summary, statistical, or aggregate form.

**Definitions**

**De-Identified Data** – Prescription-level data with identifiers blinded for patients, prescribers and pharmacies.

**Statistics & Aggregate Data** – Data which is compiled at an aggregated level such that individual prescription records are not identifiable. Example – Number of prescriptions by county

**De-Identified Data**
1. De-identified OARRS data is intended to be used for (bona fide) research projects.
2. De-identified OARRS data is not public record.
3. Researchers not associated with a State agency must submit a research protocol and an IRB approval.
4. Researchers associated with a State agency must submit a request in writing signed by their agency director.
5. All researchers must sign a Memorandum of Understanding.
6. Protocols/Requests/MOUs must include:
   a. The reason for the study and anticipated outcome (i.e., publication, presentation at scientific meeting, etc.).
   b. Agreement that use of the data is limited to the research project terms. If data is to be re-used, another approval is required.
c. Agreement that the data cannot be transferred/shared with anyone outside of the specific research project for which it is approved.

d. Agreement that research results will be reported to the Board of Pharmacy and that the Board of Pharmacy may use the results for Board related purposes (e.g. reports to legislature).

e. Research results may be published with prior approval of the Director of OARRS; however, de-identified data may not be released as part of the publication.

7. De-identified data will be released in standard, quarterly data files. Custom de-identified files will not be generated.

Statistics and Aggregate Data

1. Director of OARRS will develop a process for validating statistics and aggregate data.

2. All statistics and aggregate data will be validated using the validating process.

3. Preliminary statistics and aggregate data may be released to Board employees or other state agencies with a notice that emphasizes the data has not been validated and should not be used in any publication, speech, presentation or otherwise publicly released. An estimated timeframe for validation of the data shall be included.

   a. Any electronically transmitted or printed materials containing preliminary statistics or aggregate data must be accompanied by the following verbiage, printed in red, bold typeface in a conspicuous manner: This document contains preliminary OARRS statistics or aggregate data. This data has not been verified for accuracy and is subject to revision. The data has not received final approval by the Director of OARRS and is provided on the condition that it is used for discussion purposes only and shall not be otherwise publicly released.

4. Director of OARRS will develop a process for organizing and storing statistics and aggregate data. This process shall include an index, description of the data, validation status of the data, requests for the data or description of where the data has been published (e.g., OARRS/Board web page), and methods for reproducing the data (e.g., queries, Tableau workbooks). Requests will be handled in the following manner:

   a. Requests for OARRS statistics or aggregate data will be made using a Board request form

   b. Requests may be made by Board staff, other state agencies, or the public.

   c. Requests from the public are limited to existing validated data. Requests for new statistics or aggregate data may not be accepted from the public.

   d. Prior to releasing statistics or aggregate data, staff shall validate that no unit of data provided represents fewer than five patients, prescribers or pharmacies. In the event that a unit of data does represent fewer than five patients, prescribers or pharmacies, values may be redacted, or the data may be represented in larger groupings.
e. Time frames for data will be no less than one month. Data shall be grouped in standard years, months or quarters.

f. Drugs will be identified by generic name only. Specific brands will not be identified.

g. Requests for new statistics must be requested a minimum of ten business days in advance. Staff will notify requestor as soon as it is determined whether additional time is needed to fulfill the request.

h. Upon receiving a request, staff will research existing verified data to determine if any can be used as-is or whether modifications are required to fulfill the request.

The motion was seconded by Mr. Passafume and approved by the Board: Aye-5.

R-2017-321 The Board received a request for approval to Ohio Administrative Code Rule 4729-3-04(B) requesting that Syed-Rehan Ashfaq Hussain, PhD, Intern (06-013848) receive an Intern license extension. Mr. Passafume moved that the Board approve the request until October 31, 2017. The motion was seconded by Ms. Marchal and approved by the Board: Aye-5.

R-2017-322 Ms. Rudell moved that the meeting be adjourned. The motion was seconded by Mr. Passafume and approved by the Board: Aye-6.

4:48 p.m. The meeting was adjourned.

Michael A. Moné, RPh, President

Date

Steven W. Schierholtz, Esq., Executive Director

Date