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March 2013

RECORD OF THE PROCEEDINGS

FY 2013

Minutes of the March 4-5, 2013 Meeting of the Ohio State Board of Pharmacy

Monday, March 4, 2013

10:00 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:

Brian M. Joyce, R.Ph., *President*; Kevin J. Mitchell, R.Ph., *Vice-President*; Troy A. Gahm, R.Ph.; Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph. and Kilee S. Yarosh, R.Ph.

Also present were Kyle Parker, Executive Director; Tracy Nave, Director of Legal Affairs; Danna Droz, Prescription Drug Monitoring Program Director.

10:04 a.m. The Board Members and staff introduced themselves to the audience, and the audience members introduced themselves to the Board.

Mr. Parker presented the Legislative Report and Pharmacy Board Budget Testimony update.

Mr. Mitchell presented House Bill 44 Testimony Report update on Emergency Dispensing.

Ms. Droz presented the Ohio Automated Prescription Reporting System update.

The Board responded to comments provided by the audience.

Mr. Parker provided the Licensing Report.

Mr. Gahm stated there was no Nursing Board CPG Committee meeting report and that the next meeting will be held in June 2013.

Lora Miller, representing the Ohio Council of Retail Merchants, requested that the Board consider issues related to pharmacists administering medications. The Board requested Lora Miller send them further information about the topic.

10:49 a.m. The Board recessed briefly.

11:04 a.m. The meeting reconvened in Room South B&C.

Mr. Parker presented an update related to House Bill 284 (Physician Assistants), which was addressed in the February Board of Pharmacy Newsletter.

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Ms. Droz provided an update related to Senate Bill 301 (OARRS Pharmacist Delegates), which will become effective on March 13, 2013 and was also addressed in the February Board of Pharmacy Newsletter.

- **11:15 a.m.** The Board met with Ratna Palakodeti, M.D., Stan Anderson, M.D. and Ms. Ann Spicer, Ohio Academy of Family Physicians, for a presentation regarding patient safety concerns with the current retail pharmacy practice of automatic refilling prescription medications. They also discussed ideas to improve the Ohio Automated Rx Reporting System and concerns regarding over-regulation of obesity medications.
- 12:05 p.m. The Board recessed for lunch.

1:30 p.m. The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Alan Schwepe to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of John P. Thomas, R.Ph. (03-2-15436) Brookfield, Ohio.

- 2:09 p.m. Mr. Gahm moved that the Board recess in order to consider this 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. Kolezynski and a roll-call vote was conducted by President Joyce as follows: Huwer – yes; Gahm – yes; Kolezynski – yes; Mitchell – yes; Yarosh – yes.
- 2:23 p.m. The recess ended and the meeting was opened to the public.
- 3:07 p.m. The hearing continued.

Mr. Gahm moved that the Board recess in order to consider this 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. Huwer and a roll-call vote was conducted by President Joyce as follows: Huwer – yes; Gahm – yes; Kolezynski – yes; Mitchell – yes; Yarosh – yes.

3:30 p.m. The recess ended and the meeting was opened to the public.

<u>R-2013-141</u> The Board continued the hearing in the matter of John P. Thomas, R.Ph. (03-2-15436) Brookfield, Ohio, until December 2013.

The Board recessed briefly.

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3:39 p.m. The meeting reconvened in Room South B&C.

<u>R-2013-142</u> The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that **Erin K. Scott**, R.Ph. (03-1-24797) Cincinnati, Ohio, be the responsible person for the following pharmacies:

> Drake Center, Inc., Cincinnati, Ohio (02-0592200) HealthSouth Rehabilitation Hospital at Drake, Cincinnati, Ohio (02-2169400)

After discussion, Mr. Kolezynski moved that the Board approve the request for a period of one year. The motion was seconded by Ms. Yarosh and approved by the Board: Aye – 5.

- **R-2013-143** Mr. Parker introduced the topic of reappointment of the Clinical Pharmacist to the Nursing Board CPG Committee. After discussion, Mr. Kolezynski moved to reappoint Clinical Pharmacist **Frank Joseph Krivanek**, R.Ph. (03-2-15199) to the CPG Committee for a period of 3 years. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 5.
- <u>R-2013-144</u> Mr. Parker led a discussion on out-of-state central-fill sites. After discussion, Mr. Kolezynski moved to authorize the Board Executive Director and Assistant Executive Director to approve the license applications of out-of-state central-fill sites, pending live inspection of the receiving Ohio site. The Executive Director will bring applications for out-of-state central-fill sites with uncommon issues to the Board for review. The motion was seconded by Ms. Yarosh and approved by the Board: Aye 5.
- 3:59 p.m. The Board discussed Mr. Joyce's upcoming 3-day ACPE Evaluations Team site visit to Cedarville University. Mr. Joyce appointed Mr. Mitchell.
- <u>R-2013-145</u> Mr. Joyce announced the following Settlement Agreement has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY (Docket Number D-120828-262)

In The Matter Of:

Buckeye Family Medicine, Inc. TDD PMC Applicant c/o Rosalie A. Kuriakose, M.D. 1570 Cleveland Ave. Columbus, OH 43211

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This Settlement Agreement is entered into by and between Buckeye Family Medicine, Inc. and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Buckeye Family Medicine, Inc. enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, the right to appeal. Buckeye Family Medicine, Inc. acknowledges that by entering into this Agreement it has waived its rights under Chapter 119. of the Revised Code.

WHEREAS, the State Board of Pharmacy is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code, or may impose a monetary penalty on the license holder, for violation of any of the enumerated grounds of Section 4729.57 of the Ohio Revised Code.

WHEREAS, Buckeye Family Medicine, Inc. is an unlicensed applicant for a license to be a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification in the State of Ohio.

WHEREAS, on or about August 28, 2012, pursuant to Chapter 119. of the Ohio Revised Code, Buckeye Family Medicine, Inc. was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, a hearing was continued by the Board. The August 28, 2012, Notice of Opportunity for Hearing contains the following allegations or charges:

- (1) Records of the Board of Pharmacy indicate that on or about June 18, 2011, Rosalie Kuriakose was the Medical Director of Buckeye Family Medicine, Inc, located at 1570 Cleveland Ave., Columbus, Ohio 43211 and that on said date, Rosalie Kuriakose submitted an application for registration as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification.
- (2) The Medical Director of Buckeye Family Medicine, Inc. has failed to furnish satisfactory proof to the Board that she shall be in control of the facility that is owned and operated solely by one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery. Specifically, Buckeye Family Medicine, Inc. is owned by The Buckeye Family Medicine Inc. Creditor Trust. This trust was created to hold all of Buckeye's shares as well as all other property or proceeds which may be acquired. Such is contrary to Section 4729.552(B)(1) of the Ohio Revised Code and Rule 4731-29-01(B) of the Ohio Administrative Code.

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Buckeye Family Medicine, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated August 28, 2012.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing, Buckeye Family Medicine, Inc. knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) The Ohio State Board of Pharmacy hereby permits Buckeye Family Medicine, Inc. to withdraw its application as a Terminal Distributor of Dangerous Drugs.
- (B) The Ohio State Board of Pharmacy hereby dismisses the above mentioned disciplinary action against Buckeye Family Medicine, Inc. relating to its application as a Terminal Distributor of Dangerous Drugs and its compliance with the State's applicable rules and regulations.

Buckeye Family Medicine, Inc. acknowledges that it has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Buckeye Family Medicine, Inc. waives any and all claims or causes of action it may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Buckeye Family Medicine, Inc. waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

This Agreement embodies the entire agreement between and of the parties. There are no express or implied promises, guarantees, terms, covenants, conditions, or obligations other than those contained herein; and this agreement supersedes all previous communications, representations or agreements, either verbal or written, between the parties.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

Buckeye Family Medicine, Inc. c/o Rosalie A. Kuriakose, M.D., Respondent 02/28/2013 Date of Signature

Todd A. Ernsberger, Attorney for Respondent

02/28/2013 Date of Signature 77 South High Street, Room 1702 RECORD OF THE PROCEEDINGS Columbus, Ohio 43215-6126 FY 2013 174

	03/04/2013
Brian M. Joyce, President, Ohio State Board of Pharmacy	Date of Signature
	03/04/2013
Alan P. Schwepe, Ohio Assistant Attorney General	Date of Signature

<u>**R-2013-146</u>** Mr. Joyce announced the following Settlement Agreement has been signed by all parties and is now effective.</u>

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY (Docket Number D-120424-261)

In The Matter Of:

Buckeye Family Medicine, Inc. TDD PMC Applicant c/o Rosalie A. Kuriakose, M.D. 2575 W. Broad St. Columbus, OH 43204

This Settlement Agreement is entered into by and between Buckeye Family Medicine, Inc. and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Buckeye Family Medicine, Inc. enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, the right to appeal. Buckeye Family Medicine, Inc. acknowledges that by entering into this Agreement it has waived its rights under Chapter 119. of the Revised Code.

WHEREAS, the State Board of Pharmacy is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, refuse to renew any license issued to a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code, or may impose a monetary penalty on the license holder, for violation of any of the enumerated grounds of Section 4729.57 of the Ohio Revised Code.

WHEREAS, Buckeye Family Medicine, Inc. is an unlicensed applicant for a license to be a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification in the State of Ohio.

WHEREAS, on or about August 24, 2012, pursuant to Chapter 119. of the Ohio Revised Code, Buckeye Family Medicine, Inc. was notified of the allegations or charges against it,

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its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, a hearing was continued by the Board. The August 24, 2012, Notice of Opportunity for Hearing contains the following allegations or charges:

- (1) Records of the Board of Pharmacy indicate that on or about June 18, 2011, Rosalie Kuriakose was the Medical Director of Buckeye Family Medicine, Inc, located at 2575 W. Broad St., Columbus, Ohio 43204 and that on said date, Rosale Kuriakose submitted an application for registration as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification.
- (2) The Medical Director of Buckeye Family Medicine, Inc. has failed to furnish satisfactory proof to the Board that she shall be in control of the facility that is owned and operated solely by one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery. Specifically, Buckeye Family Medicine, Inc. is owned by The Buckeye Family Medicine Inc. Creditor Trust. This trust was created to hold all of Buckeye's shares as well as all other property or proceeds which may be acquired. Such is contrary to Section 4729.552(B)(1) of the Ohio Revised Code and Rule 4731-29-01(B) of the Ohio Administrative Code.

Buckeye Family Medicine, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated August 24, 2012.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing, Buckeye Family Medicine, Inc. knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) The Ohio State Board of Pharmacy hereby permits Buckeye Family Medicine, Inc. to withdraw its application as a Terminal Distributor of Dangerous Drugs.
- (B) The Ohio State Board of Pharmacy hereby dismisses the above mentioned disciplinary action against Buckeye Family Medicine, Inc. relating to its application as a Terminal Distributor of Dangerous Drugs and its compliance with the State's applicable rules and regulations.

Buckeye Family Medicine, Inc. acknowledges that it has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Buckeye Family Medicine, Inc. waives any and all claims or causes of action it may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Buckeye Family

Medicine, Inc. waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

This Agreement embodies the entire agreement between and of the parties. There are no express or implied promises, guarantees, terms, covenants, conditions, or obligations other than those contained herein; and this agreement supersedes all previous communications, representations or agreements, either verbal or written, between the parties.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

Buckeye Family Medicine, Inc. c/o Rosalie A. Kuriakose, M.D., Respondent

Todd A. Ernsberger, Attorney for Respondent

Brian M. Joyce, President, Ohio State Board of Pharmacy

Alan P. Schwepe, Ohio Assistant Attorney General

02/28/2013 Date of Signature

02/28/2013 Date of Signature

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02/04/2013 Date of Signature

03/04/2013 Date of Signature

<u>R-2013-147</u> Mr. Joyce announced the following Settlement Agreement has been signed by all parties and is now effective.

SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY (Docket Number D-121114-274)

In The Matter Of:

HEATHER HUNT KENNEDY, R.Ph.

6514 Winston Ct. E. Columbus, Ohio 43235 (R.Ph. No. 03-3-30848)

This Settlement Agreement is entered into by and between Heather Hunt Kennedy and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code. Heather Hunt Kennedy voluntarily enters into this Agreement being fully informed of her rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel, the right to a formal adjudication hearing on the issues contained herein, and the right to appeal. Heather Hunt Kennedy acknowledges that by entering into this Agreement she has waived her rights under Chapter 119. of the Revised Code.

Whereas, the Board is empowered by Section 4729.16 of the Ohio Revised Code to suspend, revoke, limit, place on probation, refuse to grant or renew an identification card or enforce a monetary penalty on the license holder for violation of any of the enumerated grounds therein.

Whereas, Heather Hunt Kennedy is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about November 14, 2012, pursuant to Chapter 119. of the Ohio Revised Code, Heather Hunt Kennedy was notified of the allegations or charges against her, her right to a hearing, her rights in such hearing, and her right to submit contentions in writing. Heather Hunt Kennedy requested a hearing; it was scheduled and continued. The November 14, 2012 Notice of Opportunity for Hearing contains the following allegations or charges:

- (1) Records of the State Board of Pharmacy indicate that Heather Hunt Kennedy was originally licensed in the State of Ohio on June 10, 2011, pursuant to examination, and is currently licensed to practice pharmacy in the State of Ohio.
- (2) Heather Hunt Kennedy did, between September 16, 2011 and November 13, 2011, when not a registered pharmacist or pharmacy intern, dispense or sell dangerous drugs and/or otherwise engage in the practice of pharmacy, to wit: though Heather Hunt Kennedy did not renew your license to practice pharmacy, you counseled patients on drug therapy and worked under a consult agreement, all of which are under the definition of the practice of pharmacy. Such conduct is in violation of Section 4729.28 of the Ohio Revised Code.

Heather Hunt Kennedy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated November 14, 2012; however, the Board has evidence sufficient to sustain the allegations and hereby adjudicates the same.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing at this time, Heather Hunt Kennedy knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

(A) Heather Hunt Kennedy agrees to the imposition of a monetary penalty of five hundred dollars (\$500.00) due and owing within thirty days from the effective date of this Agreement. Checks should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed forms to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

If, in the judgment of the Board, Heather Hunt Kennedy appears to have violated or breached any terms or conditions of this Agreement, the Ohio State Board of Pharmacy reserves the right to, at any time, revoke probation, modify the conditions of probation, and reduce or extend the period of probation, and/or the Board may institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violation of the laws of Ohio occurring before the effective date of this Agreement.

Heather Hunt Kennedy acknowledges that she has had an opportunity to ask questions concerning the terms of this Agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Heather Hunt Kennedy waives any and all claims or causes of action she may have against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement. Heather Hunt Kennedy waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.

	01/30/2013
Heather Hunt Kennedy, R.Ph., Respondent	Date of Signature
	02/06/2013
David W. Grauer, Attorney for Respondent	Date of Signature
	03/04/2013
Brian M. Joyce, R.Ph., President, Ohio State Board of Ph	narmacy Date of Signature
	03/04/2013
Sean M. Culley, Ohio Assistant Attorney General	Date of Signature

4:00 p.m. Mr. Gahm moved that the Board go into Executive Session to consider the investigation of charges or complaints against a licensee or employee, consider the employment of a public employee, confer with Board counsel regarding 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

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seconded by Mr. Kolezynski and a roll-call vote was conducted by President Joyce as follows: Huwer – yes; Gahm – yes; Kolezynski – yes; Mitchell – yes; Yarosh – yes.

4:57 p.m. The Executive Session ended and the meeting was opened to the public.

The Board recessed for the day.

Tuesday, March 5, 2013

8:31 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:

Brian M. Joyce, R.Ph., *President*; Kevin J. Mitchell, R.Ph., *Vice-President*; Troy A. Gahm, R.Ph.; Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph. and Kilee S. Yarosh, R.Ph.

<u>R-2013-148</u> Mr. Kolezynski moved that the Board minutes of February 4-5, 2013, be approved as amended. Ms. Yarosh seconded the motion and it was approved by the Board: Aye – 5.

The Board Members and staff introduced themselves to the audience, and the audience members introduced themselves to the Board.

The Board recessed briefly.

9:50 a.m. The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Alan Schwepe to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Bethlehem Fire & Rescue, Inc. c/o Gary Richardson, D.O.** (02-0304250) Navarre, Ohio.

11:05 a.m. The Board recessed briefly.

11:10 a.m. The meeting reconvened in Room South B&C.

11:35 a.m. The hearing ended and the record was closed.

Mr. Kolezynski moved that the Board recess in order to consider this 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

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Mr. Gahm and a roll-call vote was conducted by President Joyce as follows: Huwer – yes; Gahm – yes; Kolezynski – yes; Mitchell – yes; Yarosh – yes.

- 11:50 a.m. The recess ended and the meeting was opened to the public.
- <u>R-2013-149</u> After votes were taken in public session, the Board adopted the following order in the matter of **Bethlehem Fire & Rescue, Inc. c/o Gary Richardson, D.O.** (02-0304250) Navarre, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

(Docket Number D-120512-283)

In The Matter Of:

BETHLEHEM FIRE AND RESCUE, INC. C/O GARY RICHARDSON, D.O.

34 S. Main St. Navarre, Ohio 44662 (Ohio Terminal Distributor License No. 02-0304250)

INTRODUCTION

The Matter of Bethlehem Fire and Rescue, Inc. came for hearing on March 5, 2013, before the following members of the Board: Brian M. Joyce, R.Ph.; (presiding); Troy A. Gahm, R.Ph.; Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Kevin J. Mitchell, R.Ph. and Kilee S. Yarosh, R.Ph.

Edward T. Cain, Public Member, Absent Michael A. Moné, R.Ph., Board Member, Absent

Bethlehem Fire and Rescue, Inc. were represented by Alfred Schrader. The State of Ohio was represented by Alan M. Schwepe, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

None

Respondent's Witnesses:

- Brad Shaffer, Paramedic, Bethlehem Fire and Rescue, Inc.
- Stanley Josefczyk, Chief, Bethlehem Fire and Rescue, Inc.
- 3. David Gallagher, Ohio State Board of Pharmacy

State's Exhibits:

- 1. Notice of Opportunity for Hearing [12-05-12]
- 1A-1D. Procedurals
- 2. Paramedic Drug Check Off Sheet [not dated]
- 3. Paramedic Drug Check Off Sheet [01-14-08 to 07-30-10]
- 4. Paramedic Drug Check Off Sheet [various dates]
- 5. Rescue Squad Report [03-20-12]
- 6. Operating Log [02-20-12 to 03-27-12]
- 7. Bethlehem Fire and Rescue, Inc., EMS Run Report [03-20-13]
- 8. EMS Trip Sheet with Attachments [03-20-12]
- 9. Moore Medical Invoices [08-16-12 and 08-17-12]

Respondent's Exhibits:

- A. Paramedic Drug Check Off Sheet [01-14-08 to 07-10-08]
- B. Controlled Drug Log [01-14-08]
- C. Missing Drug Item List [not dated]
- D. Moore Medical Invoice [08-16-12]
- E. Letter from Stanley Josefczyk, Chief [02-13-13]
- F. Affidavit of Gary Richardson, D.O., F.A.C.E.P [02-22-13]

FINDINGS OF FACT

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

(1) Records of the Board of Pharmacy indicate that Bethlehem Fire and Rescue, Inc. are licensed with the State Board of Pharmacy as a Terminal Distributor of Dangerous Drugs. Records further reflect during the relevant time periods stated herein, Gary Richardson, D.O. was the Responsible Person pursuant to Rule 4729-5-11 of the Ohio Administrative Code and Sections 4729.27 and 4729.55 of the Ohio Revised Code.

(2) Bethlehem Fire and Rescue, Inc. did, on or about May of 2012, fail to notify the Ohio State Board of Pharmacy by telephone immediately upon the discovery of the theft or significant loss of dangerous drugs or controlled substances, to wit: While conducting a "Drug Check" in May of 2012, Paramedic Stanley J. Josefczyk, Sr., as the person responsible for the day-to-day operations of Bethlehem Fire and Rescue, Inc., determined that EMS was missing two vials of midazolam 1mg/ml, 2 vials of lorazepam 2mg/ml, 2 morphine 5mg/ml syringes, 5 vials of adenosine 3mg/ml Solution for Injection, 1 atropine 0.1mg/ml syringe, and 2 vials of sodium bicarbonate 50meq/50ml for injection. This was not reported to the Ohio State Board of Pharmacy until August 3, 2012. Such conduct is in violation of Rule 4729-9-15(A) of the Ohio Administrative Code. (3) Bethlehem Fire and Rescue, Inc., between July 31, 2010 and August 7, 2012, failed to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. Specifically, Bethlehem Fire and Rescue, Inc. and Stanley J. Josefczyk, Sr., as the responsible person delegate for the EMS' day-to-day operations pursuant to O.A.C. Section 4729-33-03, stopped using a Board approved tamper evident dangerous drugs security system, which actions led to the theft or loss of dangerous drugs. Such conduct, if proven, indicates that the EMS ceased to satisfy the qualifications of a terminal distributor of dangerous drugs as set forth in Section 4729.55 of the Ohio Revised Code and proscribed by Section 4729.57 of the Ohio Revised Code.

(4) Bethlehem Fire and Rescue, Inc., between July 31, 2010 and August 7, 2012, failed to provide supervision and control of effective and approved controls and to deter and detect theft and diversion of dangerous drugs as required by O.A.C. 4729-9-11. Specifically, Stanley J. Josefczyk, Sr., as the responsible person delegate for the EMS' day-to-day operations pursuant to O.A.C. Section 4729-33-03, permitted access to Bethlehem Fire and Rescue, Inc. dangerous drug stock without assuring approved security procedures were in place, and drug counts were properly monitored. Such conduct, if proven, is in violation of Rule 4729-9-11 of the Ohio Administrative Code.

(5) Bethlehem Fire and Rescue, Inc., between July 31, 2010 and August 7, 2012, failed to keep records of dangerous drug receipts, for three years, at the place where the dangerous drugs are located, and without first sending a written request to the State Board of Pharmacy, as required by O.A.C. 4729-9-22(E). Specifically, Stanley J. Josefczyk, Sr., as the responsible person delegate for the EMS' day-to-day operations pursuant to O.A.C. Section 4729-33-03, kept Moore Medical wholesale purchase receipts at his unlicensed personal residence. Such conduct, if proven, is in violation of Rule 4729-9-22(E) of the Ohio Administrative Code.

CONCLUSIONS OF LAW

(1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (5) of the Findings of Fact constitute violating a rule of the Board as provided in Division (A)(2) of Section 4729.57 of the Ohio Revised Code.

(2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (5) of the Findings of Fact constitute violating provisions of the this Chapter as provided in Division (A)(3) of Section 4729.57 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.56 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby imposes a monetary penalty of

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two thousand dollars (\$2,000.00) on Bethlehem Fire and Rescue, Inc. and payment in full is due and owing within thirty days of the mailing of this Order. The remittance should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

Pursuant to Section 4729.56 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby places on probation for a period of one year the Terminal Distributor License, License No. 02-0304250, held by Bethlehem Fire and Rescue, Inc. effective as of the date of the mailing of this Order. The terms of probation are as follows:

(A) Bethlehem Fire and Rescue, Inc. must obtain a final inspection by a Board of Pharmacy agent within 30 days from the effective date of this order.

(B) Bethlehem Fire and Rescue, Inc. must submit appropriate paperwork to change the primary site contact to Brad Shaffer within 30 days from the effective date of this order.

(C) Bethlehem Fire and Rescue, Inc. must consult with and follow all recommendations of the Board of Pharmacy on destruction of dangerous drugs.

(D) Bethlehem Fire and Rescue, Inc. must not violate the drug laws of Ohio, any other state, or the federal government.

(E) Bethlehem Fire and Rescue, Inc. must abide by the rules of the State Board of Pharmacy.

(F) Bethlehem Fire and Rescue, Inc. must comply with the terms of this Order.

(G) Bethlehem Fire and Rescue Inc.'s license is deemed to be not in good standing until successful completion of the probationary period.

(H) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.56 of the Ohio Revised Code.

Bethlehem Fire and Rescue, Inc. is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

Richard Kolezynski moved for Findings of Fact; Margaret Huwer seconded the motion. Motion passed (Aye-5/Nay-0).

Troy Gahm moved for Conclusions of Law; Richard Kolezynski seconded the motion. Motion passed (Aye-5/Nay-0).

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Kilee Yarosh moved for Action of the Board; Margaret Huwer seconded the motion. Motion passed (Aye-5/Nay-0).

- 11:55 a.m. The Board recessed briefly.
- <u>11:55 a.m.</u> The meeting reconvened in Room South B&C.
- <u>R-2013-150</u> Mr. Kolezynski moved that the Board receive Per Diem as follows:

3/4	3/5	Total
0	0	0
1	1	2
1	1	2
1	1	2
1	1	2
1	1	2
0	0	0
1	1	2
	0 1 1 1 1 1	0 0 1 1 1 1 1 1 1 1 1 1 1 1

Mr. Gahm seconded the motion and it was approved by the Board: Aye – 5.

- **<u>R-2013-151</u>** Mr. Kolezynski moved that the meeting be adjourned at the conclusion of introductions to and discussion with candidates for licensure by reciprocity. The motion was seconded by Ms. Huwer and approved by the Board: Aye 5.
- 11:56 a.m. The Board recessed for lunch.
- **1:30 p.m.** The Board reconvened in Room South A, 31st Floor of the Vern Riffe Center for Government and the Arts. The following candidates for licensure by reciprocity introduced themselves to the Board, and then participated in a discussion of pharmacy laws and rules with Mr. Rob Amiet, *Compliance Specialist* and the Board.
 - Syed A. Absar Rachel Baker Mary E. Beimesch Cassandra Nicole Campbell Deborah K. Estanislao Christopher Mark Hale Georgia A. Hanna-Ghattas John Aloysius Hartnett Tiffanie Marie Hennard Carrie Lynn Hinerman Felicia A. Fong Kong Elizabeth A. Papas
 - Virginia Maine Kentucky Kentucky Florida West Virginia New Jersey New Jersey Michigan West Virginia Florida Kentucky

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	Trusharkumar A. Parekh	Michigan
	Thomas C. Popelka	Indiana
	Vijayadurga Ryali	Connecticut
	Cynthia Sens Rosales	Virginia
	Jennifer A. Siegfried	Pennsylvania
	Betthany Marie Thomas	Louisiana
	Marshall Tuetken	Wisconsin
	Olga Lucia Zytcer	Massachusetts
Brian M. Jo	Arter R.Ph., President	Date:5 - 6 - 1)
	Blevale	Date: 5-6-13

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