Minutes of the March 4-5, 2014
Meeting of the Ohio State Board of Pharmacy

Tuesday, March 4, 2014

9:02 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:


Also present were Kyle Parker, Executive Director; Tracy Nave, Director of Legal Affairs; Chad Garner, Director of OARRS; Eric Griffin, Compliance Supervisor; Jennifer Utterdyke, Director of Internship and Licensing; Cameron McNamee, Legislative Affairs Liaison and Charissa Payer, Assistant Attorney General.

Ms. Yarosh 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 Ms. Marchal and a roll-call vote was conducted by President Mitchell as follows: Cain – yes; Ferris – yes; Huwer – yes; Kolezynski – yes; Marchal – yes and Yarosh – yes.

9:18 a.m. The Executive Session ended and the meeting was opened to the public.

R-2014-145

Mr. Kolezynski moved that the Board accept the request for voluntary surrender of the intern license of Philip Rocci, Columbus, Ohio and allowed a sufficient amount of time for preparation and approval of appropriate voluntary surrender paperwork. The motion was seconded by Mr. Cain and approved by the Board: Aye – 6.

Ms. Ferris stated there was no Nursing Board CPG report, and the next committee meeting is scheduled to occur in May 2014.

Ms. Huwer provided the Medical Board PAPC report from the February 11, 2014 meeting.

Mr. McNamee presented the Legislative Report.

9:20 a.m. Michael Moné, R.Ph., Vice-President, arrived at the meeting.
R-2014-146 Mr. Kolezynski moved that that Board approve Rule 4729-7-02 as amended. The motion was seconded by Ms. Marchal and approved by the Board: Aye – 7.

Antonio Ciaccia, Ohio Pharmacists Association, and Lora Miller, Ohio Council of Retail Merchants, addressed the Board.

Mr. Griffin provided the Compliance and Enforcement update.

Ms. Utterdyke presented the Licensing update.

Mr. Garner provided the OARRS/I.T. report.

R-2014-147 The Board received a request for an approval to Ohio Administrative Code Rule 4729-5-11 (A) (1) requesting that Dan Wearsch, R.Ph. (03-3-15872) Vienna, Ohio, be the responsible person for the following pharmacies:

Pharmacy Care Associates, Inc., Canfield (02-1069150)
Canfield Pharmacy Care, Canfield (02-2186850)

After discussion, Mr. Moné moved that the Board approve the request for a period of one year. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 7.

R-2014-148 The Board received a request to withdraw the Pain Management Clinic application of Pinnacle Interventional Pain & Spine Consultants, Parma, Ohio. Mr. Kolezynski moved that the request to withdraw the application be accepted. The motion was seconded by Mr. Cain and approved by the Board: Aye – 7.

Mr. Mitchell introduced audience member Bill Kover as the NABP District 4 Representative.

9:58 a.m. The Board recessed briefly.

10:09 a.m. The meeting reconvened in Room South B&C.

The Board was joined by Assistant Attorney General Charissa Payer to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of Erica Minha Lee, Columbus, Ohio.

10:55 a.m. The Board recessed for the Public Rules Hearing.

The public hearing concerning the proposed new and amended rules began in Room South B&C, 31st Floor of the Riffe Center, with the following members in attendance:
The meeting rules hearing ended.

The meeting and hearing in the matter of **Erica Minha Lee** reconvened in Room South B&C.

**11:40 a.m.** The Board recessed for lunch.

**1:00 p.m.** The meeting reconvened in Room South B&C.

Mr. Moné 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. Kolezynski and a roll-call vote was conducted by President Mitchell as follows: Cain – yes; Ferris – yes; Huwer – yes; Kolezynski – yes; Marchal – yes; Moné – yes; and Yarosh – yes.

**1:30 p.m.** The executive session ended and the meeting was opened to the public.

The Board convened 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 Ms. Terri Ghitman, OARRS Pharmacist:

- Dina H. Abdelhalim, Texas
- Cherice M. Allison, Tennessee
- Erick Matthew Alsvig, Illinois
- Brian Michel Baker, Indiana
- Joelle Marie Beiswenger, West Virginia
- Jennifer Larsen Campbell, North Carolina
- Eva Chan, Michigan
- Rachel Natisha Chandra, Florida
- Leah Alexandra Comis, West Virginia
- Chad James Forinash, Missouri
- Kristin Monnig Gentry, North Carolina
- Angela Nicole Hamman, Arizona
- Troy William Kienzle, Texas
- Kisito Nzinkenzi Kikam, Arkansas
- Erin Caitlin Latta, Indiana
Kimberly Ann Peterson                      Pennsylvania
John Proctor Redden                        Alabama
Niyati C. Shah                             Tennessee
Husam A. Sweidan                           Washington
Diem Ngoc Tran                            Florida

1:53 p.m. The meeting and hearing in the matter of Erica Minha Lee, Columbus, Ohio reconvened in room South B&C.

3:30 p.m. The hearing ended and the record was closed.

Ms. Yarosh 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 Mitchell as follows: Cain – yes; Ferris – yes; Huwer – yes; Kolezynski – yes; Marchal – yes; Moné – yes; Yarosh – yes.

4:12 p.m. The recess ended and the hearing was opened to the public.

R-2014-149 After votes were taken in public session, the Board adopted the following order in the matter of Erica Minha Lee, Columbus, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY
(Case Number 2013-1889)

In The Matter Of:

ERICA MINHA LEE, R.Ph.
1350 Neil Ave. Apt. E
Columbus, OH 43201
(Intern Number 06-0-09852)

INTRODUCTION


Erica Minha Lee was represented by Daniel D. Connor. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.
SUMMARY OF EVIDENCE

State’s Witnesses:
1. Erica Lee, Respondent
2. Kevin E. Flaharty, Ohio State Board of Pharmacy

Respondent’s Witnesses:
1. Erica Lee, Respondent
2. Christine Harrison

State’s Exhibits:
1. Summary Suspension Order/Notice of Opportunity for Hearing 10-29-13
1A-1C. Procedurals
2. Amended Summary Suspension Order/Notice of Opportunity for Hearing 11-08-13
3. Notarized Statement of Erica Lee 10-26-13
4. Notarized Statement of Philip D. Rocci 10-26-13
5. Copy of two prescriptions in the name of Matt Allen for Norco 10/325 RX #4460161-01600514; Computer notes; Amoxicillin 500 RX # 6118639-01600514; Patient Profile Screen 08-31-13
6. Copy of two prescriptions in the name of Jeremy Miller for Norco 04-27-13 10/325 RX #4458544-01600514; Fill History for Jeremy Blanton; 11-04-13 Computer generated drug ID screen for HYDROcodone-ACETAMINOPHEN 10-325; RX in the name of Jeremy Miller for Amoxicillin 500mg; RX # 6104725-01600514; Computer generated drug ID screen for AMOXICILLIN 500mg; Computer Patient ID Screen 08-31-13
7. Copy of two prescriptions in the name of Andrew Lowell for Norco 09-14-13 10/325 RX #4460343-01600514; Computer generated drug ID screen for HYDROcodone-ACETAMINOPHEN 10-325; RX for Amoxicillin 500mg RX #6120080-01600514; two computer prescription Information screens for Andrew Lowell 08-31-13
8. Copy of two prescriptions in the name of Mike Green for Norco 05-18-13 10/325 RX #4458812-01600514; two computer generated Drug ID Screens for HYDROcodone-ACETAMINOPHEN; computer patient information screen for Mike Green; RX #6107071-0165514 for Amoxicillin 500mg; Dangerous Drug Distribution Inspection Report at Kroger 11-04-13
9. CVS/pharmacy Telephone Order Prescription Pad for Jeremy Blanton for Norco 10-325; RX C0364912; Patient Profile for Jeremy Blanton; Dangerous Drug Distributor Inspection Report at CVS/Pharmacy 05-29-13
11. Copies of two prescriptions in the name of James Hagerton 10-03-13 For Amoxicillin 500mg, RX #6122357-01600514; Norco 10/325mg RX #4460570-01600514; Computer general drug ID screen for
HYDROcodone-ACETAMINOPHEN; Patient profile for James Hagerton; Photo of respondent in Kroger pharmacy; Dangerous Drug Distributor Inspection Report at Kroger Pharmacy 10-21-13

13. Electronic Transfer Hard Copy for RX #4460052-01600818 ; 10-03-13
    Computer generated drug ID screen for HYDROcodone-ACETAMINOPHEN; Photo of respondent in Kroger Pharmacy #818; 10-26-13

Respondent's Exhibits:
A. Pharmacists Rehabilitation Organization Inc. Contract 12-17-13
B. Report – Katherine A. Kelley, OSU College of Pharmacy; Stipulations regarding readmittance 01-15-14
C. Reports – Professors of Pharmacy at Ohio State University 02-24-13 and 02-25-13
D. Questhouse Chart 11-11-13 to 12-09-13
E. Questhouse Report 02-05-14
F. Talbot Hall Progress Report 02-14-14
G. Report – Noelle Arduini, Talbot Hall 02-05-14
H. Meeting Attendance Records 11-02-13 to 03-02-14
I. Urine Drug Screen Reports 02-20-14 and 03-03-14
J. Report – Mary S. McDaniel, Pro Advocate 02-23-14
K. Report – Linda Dennis, NA Sponsor 02-23-14

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 Erica Minha Lee was originally licensed as an intern in the State of Ohio on December 23, 2010 and her license to practice in Ohio was Summarily Suspended effective October 29, 2013.

(2) Erica Minha Lee has admittedly abused hydrocodone/APAP a Schedule III Controlled Substance, and removed drugs under false pretenses from the pharmacy where she works.

(3) The continuation of Erica Minha Lee’s professional practice presents a danger of immediate and serious harm to others, to wit: Erica Minha Lee has admitted that she knowingly accepted fraudulent prescriptions for controlled substances and other dangerous drugs. Erica Minha Lee filled these prescriptions and admittedly provided these drugs to her boyfriend, a self-admitted opiate addict. Such conduct indicates that
Erica Minha Lee is within the ambit of Sections 3719.121 and/or 4729.16 of the Ohio Revised Code.

(4) Erica Minha Lee did, on or around October 3, 2013, knowingly sell or offer to sell a dangerous drug when the conduct was not in accordance with Chapters 2925., 3719., 4729., and 4731. of the Ohio Revised Code, to wit: Erica Minha Lee admittedly provided 60 tablets of hydrocodone/APAP 10/325 mg, a controlled substance, to her boyfriend without a legitimate prescription. Such conduct is in violation of Sections 2925.03 and 4729.51 of the Ohio Revised Code.

(5) Erica Minha Lee did, on or around October 3, 2013, knowingly sell or offer to sell a dangerous drug when the conduct was not in accordance with Chapters 4729. and 4731. of the Ohio Revised Code, to wit: Erica Minha Lee admittedly provided 14 amoxicillin 500 mg tablets, a dangerous drug, to her boyfriend without a legitimate prescription. Such conduct is in violation of Section 4729.51 of the Ohio Revised Code.

(6) Erica Minha Lee did, on or about October 12, 2013, by deception, procure the dispensing of a dangerous drug, to wit: Erica Minha Lee knowingly transferred a fraudulent prescription barring the name of a fictitious patient to another pharmacy and later retrieved the medication in question from the pharmacy. The prescription in question was Rx No. 4460570-01600514, for 60 hydrocodone/APAP 10/325 mg tablets. Such conduct is in violation of Section 2925.22 of the Ohio Revised Code.

CONCLUSIONS OF LAW

(1) The State Board of Pharmacy concludes that paragraphs (4) through (7) of the Findings of Fact constitute being guilty of a felony and gross immorality as provided in Division (A)(1) of Section 4729.16 of the Ohio Revised Code.

(2) The State Board of Pharmacy concludes that paragraphs (4) through (7) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.

(3) Further, as a result of the evidence and testimony presented, the State Board of Pharmacy concludes that paragraphs (4) and (5) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Sections 3715.52 to 3715.72 or Chapter 2925., 3719., or 4729. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

DECISION OF THE BOARD
Pursuant to Section 3719.121 of the Ohio Revised Code, the State Board of Pharmacy hereby removes the Summary Suspension Order issued to Erica Minha Lee on October 29, 2013.

(A) On the basis of the Findings of Fact and paragraph (1) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes permanently the pharmacy intern identification card, No. 06-0-09852, held by Erica Minha Lee effective as of the date of the mailing of this Order.

(B) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes permanently the pharmacy intern identification card, No. 06-0-09852, held by Erica Minha Lee effective as of the date of the mailing of this Order.

(C) On the basis of the Findings of Fact and paragraph (3) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby revokes permanently the pharmacy intern identification card, No. 06-0-09852, held by Erica Minha Lee effective as of the date of the mailing of this Order.

Michael Moné moved for Findings of Fact; Kilee Yarosh seconded the motion. Motion passed (Aye-7/Nay-0).

Margaret Huwer moved for Conclusions of Law; Melinda Ferris seconded the motion. Motion passed (Aye-7/Nay-0).

Kilee Yarosh moved for Action of the Board; Melinda Ferris seconded the motion. Motion passed (Aye-6/Nay-1).

4:13 p.m. A request for approval to Ohio Administrative Code Rule 4729-17-10 (A)(3)(F) (Adulterated Drug Packaging) was presented to the Board by Joseph Wittrock, Pharm.D., owner of LifeLine Pharmacy. The Board requested that Mr. Parker provide the Board’s decision to Dr. Wittrock after the Board has had adequate time to discuss the matter.

4:49 p.m. Betty Jones, Compliance Specialist, provided the Board with an update regarding the location of the ScriptCenter machine at the Miami Valley Hospital’s main employee entrance.

R-2014-150 Mr. Cain moved that the request from Miami Valley Hospital for an approval to install a ScriptCenter machine in the main employee entrance be denied as presented due to changes at the facility. The motion was seconded by Ms. Marchal and approved by the Board: Aye – 6/Nay – 1.
5:07 p.m. Mr. Kolezynski 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 Ms. Huwer and a roll-call vote was conducted by President Mitchell as follows: Cain – yes; Ferris – yes; Huwer – yes; Kolezynski – yes; Marchal – yes; Moné – yes and Yarosh – yes.

6:23 p.m. The Executive Session ended and the meeting was opened to the public.

R-2014-151 Mr. Moné moved that the request for settlement presented by RxPro be accepted allowing for sufficient time for the preparation and approval of settlement documentation. The motion was seconded by Ms. Yarosh and approved by the Board: Aye – 7.

R-2014-152 Mr. Moné moved that the request for settlement presented by Sterlington Pharmacy be accepted allowing for sufficient time for the preparation and approval of settlement documentation. The motion was seconded by Ms. Yarosh and approved by the Board: Aye – 7.

R-2014-153 Mr. Moné moved that the request for settlement presented by Vicksburg Pharmacy be accepted allowing for sufficient time for the preparation and approval of settlement documentation. The motion was seconded by Ms. Yarosh and approved by the Board: Aye – 7.

R-2014-154 Mr. Moné moved that the Board accept the request for voluntary surrender of the pharmacist license of Andrea Lynn Holstein, R.Ph. (03-3-25659) Dublin, Ohio and allow a sufficient amount of time for preparation and approval of appropriate voluntary surrender paperwork. The motion was seconded by Mr. Kolezynski and approved by the Board: Aye – 7.

R-2014-155 Mr. Kolezynski moved that the Board accept the request for voluntary surrender of the pharmacist license of Raymond Denuit, R.Ph. (03-1-10793) Oak Hill, Ohio and allow a sufficient amount of time for preparation and approval of appropriate voluntary surrender paperwork. The motion was seconded by Mr. Cain and approved by the Board: Aye – 7.

R-2014-156 Mr. Kolezyski moved that the request for settlement presented by Kenneth Kennedy, R.Ph. (03-1-31948) Fort Thomas, Kentucky be accepted allowing for immediate reinstatement of his pharmacy license and sixty days’ time for the preparation and approval of settlement documentation. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 7.

R-2014-157 After hearing Ms. Nave discuss the significant facts regarding the activities of the individual, Mr. Moné moved that the Board summarily suspend the license to practice
pharmacy belonging to **Heather Gaal**, R.Ph. (03-3-22051) Navarre, Ohio, pursuant to Ohio Revised Code 3719.121(B). The motion was seconded by Mr. Kolezynski and approved by a roll-call vote of the Board members participating: Aye – 7.

**R-2014-158** The Board received a request to withdraw the Terminal Distributor of Dangerous Drugs application of **Alphora Critical Care Transport, LTD**, Avon Lake, Ohio and replace it with a new application. Mr. Moné moved that because of the truthfulness of the applicant on the original application the request to withdraw and replace the application be accepted. The motion was seconded by Mr. Cain and approved by the Board: Aye – 7.

**6:26 p.m.** The Board recessed for the day.

**Wednesday, March 5, 2014**

**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:


**R-2014-159** Mr. Moné moved that the Board Minutes of February 3-4, 2014, be approved as amended. Ms. Marchal seconded the motion and it was approved by the Board: Aye – 6.

**R-2014-160** Mr. Kolezynski moved that the revised Board Minutes of January 2014, be approved as amended. Ms. Ferris seconded the motion and it was approved by the Board: Aye – 6.

**9:13 a.m.** An update regarding the OARRS project with the Medical Board was provided by Mr. Parker.

**R-2014-161** After discussion, Mr. Moné moved that the Board approve, as written, the response letter of support for the Cleveland Clinic Opiate Action Council. After discussion, the motion was seconded by Ms. Marchal and approved by the Board: Aye – 6.

**R-2014-162** Mr. Mitchell announced the following Settlement Agreement has been signed by all parties and is now effective.

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

Case Number 2013-1459

In the Matter of:

**FLORENCE PHARMACY**
This Settlement Agreement is entered into by and between Florence Pharmacy 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.

Florence Pharmacy 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. Florence Pharmacy 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, on or about October 21, 2013, pursuant to Chapter 119. of the Ohio Revised Code, Florence Pharmacy 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 scheduled and continued by the Board. The October 21, 2013 Notice of Opportunity for Hearing contains the following allegations or charges:

(1) Records of the Board of Pharmacy indicate that on or about April 8, 2013, Craig Anderson was the president of Florence Pharmacy, 3301 Veterans Drive, Florence, Alabama and that on said date, Florence Pharmacy submitted an application for registration as a Terminal Distributor of Dangerous Drugs.

(2) On or around April 18, 1996, co-owner for Florence Pharmacy, Craig Hopkins Anderson, R.Ph., was indefinitely suspended from the practice of pharmacy by the Alabama State Board of Pharmacy following an addiction to crack cocaine. In the Matter of: Craig Hopkins Anderson, Before the Alabama State Board of Pharmacy. On or around November 25, 1996, the indefinite suspension on Mr. Anderson’s license in Alabama was lifted and he was placed on probation for five (5) years with treatment and monitoring terms and conditions. On or around December 15, 2009, Craig Hopkins Anderson entered a consent agreement with the Alabama Board of Pharmacy for failure to act as a supervising pharmacist at, Leighton Pharmacy. He was placed on probation for one (1) year, and he paid an administrative fine. In the Matter of: Leighton Pharmacy, Inc. and Craig Anderson, Before the Alabama State Board of Pharmacy. Such conduct, if proven, constitutes prior discipline by a professional licensing board and or
not being of good moral character within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.

Florence Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated October 21, 2013, 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, Florence Pharmacy knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

Florence Pharmacy has submitted sufficient information to the Board to establish substantial compliance with the required qualifications of a Terminal Distributor of Dangerous Drugs and is hereby granted a license.

Florence Pharmacy 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.

Florence Pharmacy 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. Florence Pharmacy waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

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

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

(Case No. 2012-1378)

In the Matter of:

**JAMES P. DAMBROGIO, Inc.**

**c/o JAMES P. DAMBROGIO, D.O.**

212 North Main Street
Hubbard, Ohio 44425

This Settlement Agreement is entered into by and between James P. Dambrogio, Inc., c/o James P. Dambrogio, D.O. 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.
James P. Dambrogio, D.O., 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. James P. Dambrogio, D.O., 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, on or about March 27, 2013 pursuant to Chapter 119. of the Ohio Revised Code, James P. Dambrogio, D.O., 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 scheduled for September 10, 2013 and continued to December 3, 2013. The March 27, 2013 Notice of Opportunity for Hearing contains the following allegations or charges:

(1) Records of the Board of Pharmacy indicate that on or about June 17, 2011, James P. Dambrogio was the President and Responsible Person, for James P. Dambrogio, D.O., Inc., and that on said date, James P. Dambrogio, D.O., Inc. applied for registration as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification.

(2) James P. Dambrogio has failed to furnish satisfactory proof to the Board that James P. Dambrogio, D.O., Inc., complies with requirements for the operation of a pain management clinic established by Sections 4729.55 and 4729.552 of the Ohio Revised Code. To wit: James P. Dambrogio, D.O., owner and responsible person of James P. Dambrogio, D.O., Inc., entered into a Consent Agreement on November 15, 1991 with the State Medical Board of Ohio as a result of inappropriately prescribing controlled substances to twenty different patients. Such conduct, if proven, violates Section 4729.552(B)(2) of the Ohio Revised Code, Rule 4731-29-01(D) of the Ohio Administrative Code, and constitutes a failure to meet the minimum requirements for licensure as a category III terminal distributor of dangerous drugs with a pain management clinic classification. Further, such conduct is within the purview of Rule 4729-9-19 of the Ohio Administrative Code to the extent that you have been disciplined by a professional licensing board and may not be of good moral character and habits. Such is contrary to Sections 4729.55 and 4729.552 of the Ohio Revised Code, and Rules 4731-29-01 and 4729-9-19 of the Ohio Administrative Code.

James P. Dambrogio, D.O., Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 27, 2013; 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 James P. Dambrogio, D.O., Inc., knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

(A) James P. Dambrogio, D.O. is hereby permitted to withdraw his pending application for a license as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification.

(B) James P. Dambrogio, D.O., will not again apply for licensure as a Terminal Distributor of Dangerous Drugs with a Pain Management Classification in Ohio after December 23, 2013, until and unless the legal requirements for such licensure change.

(C) James P. Dambrogio, D.O. specifically agrees that the discipline outlined in paragraph (2) of the March 27, 2013 Notice of Opportunity for Hearing are disqualifying events that prohibit him from obtaining licensure as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic classification under current Ohio law.

James P. Dambrogio, D.O., Inc. acknowledges that he 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.

James P. Dambrogio, D.O., 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. James P. Dambrogio, D.O., Inc. waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

The Board was presented with a request from Mr. McNamee to approve the proposed rule for scheduling tramadol. After discussion, Ms. Yarosh moved that the Board approve the proposed rule to schedule tramadol. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 6.

Mr. Parker led a discussion about the upcoming F.D.A. meeting in Washington, D.C.

The Board discussed the request presented by Lifeline Pharmacy.

The Board recessed briefly in compliance with the statewide tornado drill, performed by Building Security.

10:04 a.m. The meeting reconvened in Room South B&C.
After further discussion of the request presented by Lifeline Pharmacy, the Board suggested that Mr. Parker notify the pharmacy of the Board’s concerns; Ms. Jones, Compliance Specialist, should inspect the pharmacy to ensure the Board’s suggestions were implemented; and, Lifeline Pharmacy should reappear in front of the Board with a revised presentation.

The Board was joined by Assistant Attorney General Charissa Payer to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of Trinity Medical Pharmacy c/o Krutika Patel, R.Ph. (02-2311700) New Port Richey, Florida.

Mr. Moné recused himself from the hearing.

11:24 a.m. The Board recessed briefly.

11:29 a.m. The meeting reconvened in Room South B&C.

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

Ms. Yarosh 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 Mitchell as follows: Ferris – yes; Huwer – yes; Kolezynski – yes; Marchal – yes; Yarosh – yes.

11:44 a.m. The recess ended and the hearing was opened to the public.

R-2014-165 After votes were taken in public session, the Board adopted the following order in the matter of Trinity Medical Pharmacy c/o Krutika Patel, R.Ph. (02-2311700) New Port Richey, Florida.

ORDER OF THE STATE BOARD OF PHARMACY
(Case Number 2013-1406)

In The Matter Of:

TRINITY MEDICAL PHARMACY
 c/o KRUTIKA PATEL, R.Ph.
9332 State Route 54, Suite 203
New Port Richey, FL 34655
INTRODUCTION

The Matter of Trinity Medical Pharmacy came for hearing on March 5, 2014, before the following members of the Board: Kevin J. Mitchell, R.Ph.; (presiding); Melinda J. Ferris, R.Ph.; Margaret A. Huwer, R.Ph.; Richard F. Kolezynski, R.Ph.; Megan E. Marchal, R.Ph. and Kilee S. Yarosh, R.Ph.

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

Trinity Medical Pharmacy was represented by Zachery Swisher. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State’s Witnesses:
1. Krutika Patel, R.Ph.
2. Chandra Galante, R.Ph., Ohio State Board of Pharmacy

Respondent’s Witness:
1. Francoise Trotman

State’s Exhibits:
1. Proposal to Deny/Notice of Opportunity for Hearing 10-21-13
2. Terminal Distributor of Dangerous Drugs Application 03-01-13
3. State of Florida Board of Pharmacy Final Order in re Deval Arvind Patel, R.Ph. 09-14-06
4. State of Florida Board of Pharmacy Motion for Board’s Final Action by Informal Hearing in re John D. Kutzko 01-25-88

Respondent’s Exhibits:
A. Trinity Medical Pharmacy LLC Background Check Not Dated
B. License Verification of John D. Kutzko and Devan Arvind Patel Not Dated
C. Trinity Medical Pharmacy LLC Compliance Program Not Dated
   Compliance Committee Meeting August 2013 08-08-13
D. Articles of Organization of Trinity Medical Pharmacy, LLC Certification of Designation of Registered Agent/Registered Office; 2012 Limited Liability Company Annual Report 01-24-11 01-24-11 05-01-12
E. Correspondence to Krutika Patel from Florida Department of Health 02-28-13
F. Florida Department of Health License Certification for Trinity 02-07-13
G. License Verification for Mark Alan Logan; Linda W. Kutzko; Jayant D. Raval Not Dated
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 on or about March 1, 2013, Krutika Patel was the responsible person for Trinity Medical Pharmacy, 9332 State Road 54, Suite 203, New Port Richey, Florida and that on said date, Trinity Medical Pharmacy submitted an application for registration as a Terminal Distributor of Dangerous Drugs.

(2) On or around March 1, 2013, applicant did knowingly make a false statement with purpose to secure the issuance of a license or registration, to wit: the application shows a negative answer to the following question: “[h]as the applicant, owner(s), Responsible Person, any agent, or any employee of the location being licensed, or any officer of the corporation, ever been the subject of disciplinary action by any state or federal agency?” Two employees of the pharmacy have previous disciplinary actions against their pharmacy licenses. On or around January 25, 1988, employee John Kutzko, R.Ph. was disciplined by the Florida Board of Pharmacy for removing approximately $4,000.00 worth of dangerous drugs from his place of employment and taking them to his residence. He had no valid prescription for any of the dangerous drugs. His pharmacy license was placed on 3 years probation, he paid a $500.00 fine and performed 12 hours of community service. Department of Professional Regulation v. John D. Kutzko, State of Florida, Board of Pharmacy DPR Case No. 0083258. On or around September 14, 2006, employee Devan Patel, R.Ph., entered into a settlement agreement with the Florida Board of Pharmacy in connection with a federal plea of guilty to knowingly selling, purchasing, or trading a drug and drug sample between the dates of October 2001 and April 2003. Department of Health v. Devan Arvind Patel, R.Ph., State of Florida Board of Pharmacy Case No. 2006-05497. Such conduct is in violation of Section 2921.13 of the Ohio Revised Code, and if proven constitutes making a false material statement in an application for registration as a terminal distributor of dangerous drugs, not being of good moral character and habits, and constitutes prior discipline by a professional licensing board pursuant within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.

(3) On or around March 1, 2013, applicant did knowingly make a false statement with purpose to secure the issuance of a license or registration, to wit: the application shows a negative answer to the following question: “[d]oes the applicant, owner(s), Responsible Person, any agent, or any employee of the location being licensed, or any
officer of the corporation, have charges pending or have a conviction of a felony or a misdemeanor other than a minor traffic violation (even if expunged or sealed)?” On or around February 6, 2006, employee Devan Patel, R.Ph., entered into a plea of guilty to one count of conspiracy to distribute sample and/or misbranded prescription drugs and was placed on two (2) years probation and ordered to complete one hundred twenty (120) hours of community service by the Federal District Court. Such conduct is in violation of Section 2921.13 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Sections 3719.03 and 4729.53 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the application submitted by Trinity Medical Pharmacy and, therefore, grants a license for a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification submitted by Trinity Medical Center on March 1, 2013.

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

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

11:45 a.m. Mr. Moné returned to the meeting after having abstained from the hearing.

R-2014-166 Mr. Moné moved that the proposed amendment to Rule 4729-5-38 be approved. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 6.

The Board was joined by Assistant Attorney General Charissa Payer to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of Wheelersburg Medical Associates c/o James M. McGinnis, D.O., Wheelersburg, Ohio.

1:16 p.m. The hearing ended and the record was closed.

1:40 p.m. 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 Wheelersburg Medical Associates c/o James M. McGinnis, D.O., Wheelersburg, Ohio.

ORDER OF THE STATE BOARD OF PHARMACY

(Case Number 2013-1663)

In The Matter Of:

WHEELERSBURG MEDICAL ASSOCIATES
c/o JAMES M. McGINNIS, D.O.
8046 Ohio River Road, Suite A
Wheelersburg, OH 45694

INTRODUCTION


Edward T. Cain, Public Member, Absent

Wheelersburg Medical Associates was not represented by counsel. The State of Ohio was represented by Charissa D. Payer, Assistant Attorney General.

SUMMARY OF EVIDENCE

State’s Witness:
1. James M. McGinnis, D.O., Respondent

Respondent’s Witness:
None

State’s Exhibits:
1A-1C. Procedurals
2. Application for Terminal Distributor License 06-18-11
3. State Medical Board of Ohio Step 1 Consent Agreement 04-05-04
4. State Medical Board of Ohio Step II Consent Agreement 07-14-04

Respondent’s Exhibits:
A. Timeline
B. Summary of Consent Agreements and Consent 04-15-04 and 07-14-04
Agreements 1 and 2
C. Curriculum Vitae of James M. McGinnis 10-93 to present
D. CEM Documentation various dates
E. Curriculum Vitae of Dr. Andrea Evans and introduction of Dr. Gabriel Updated 2-07-12
F. Medical literature re The Impaired Physician 2009
G. Letters of reference 1-13-14 to 01-30-14
H. Mailed correspondence to and from the Board of Pharmacy 11-15-13 to 02-04-14
I. Email communication Board of Pharmacy and Medical Board 02-6-14 to 02-20-14

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witness, 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 on or about June 18, 2011, James M. McGinnis, D.O., was the responsible person for Wheelersburg Medical Associates, located at 8046 Ohio River Road, Suite A, Wheelersburg, Ohio 45694, and that on June 18, 2011, Wheelersburg Medical Associates applied for registration as a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification.

(2) James McGinnis, D.O., owner, physician and responsible person of Wheelersburg Medical Associates, was disciplined by the State Medical Board of Ohio. Step I and Step II Consent Agreement In the Matter of James Martin McGinnis, D.O. and the State Medical Board of Ohio, April 15, 2004 and July 17, 2004. Such action constitutes prior discipline by a professional licensing board within the meaning of Rule 4729-9-19 of the Ohio Administrative Code and Section 4729.57 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Sections 3719.03 and 4729.53 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby approves the application submitted by Wheelersburg Medical Associates and, therefore, grants a license for a Terminal Distributor of Dangerous Drugs with a Pain Management Clinic Classification submitted by Wheelersburg Medical Associates on June 18, 2011.

Michael Moné moved for Findings of Fact; Melinda Ferris seconded the motion. Motion passed (Aye-4/Nay-3).

Michael Moné moved for Action of the Board; Melinda Ferris seconded the motion. Motion passed (Aye-6/Nay-0).
The Board recessed for lunch.

2:09 p.m.

The meeting reconvened in Room South B&C.

Mr. Kolezynski 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 and to discuss the employment of a public employee, the purchase of property and matters required to be confidential by law pursuant to Section 121.22(G)(1), (2) & (5) of the Ohio Revised Code. The motion was seconded by Ms. Marchal and a roll-call vote was conducted by President Mitchell as follows: Ferris – yes; Huwer – yes; Kolezynski – yes; Marchal – yes; Moné – yes and Yarosh – yes.

Ms. Yarosh left the meeting.

4:14 p.m.

The Executive Session ended and the meeting was opened to the public.

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Mr. Kolezynski moved that the Board receive Per Diem as follows:

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Ms. Marchal seconded the motion and it was approved by the Board: Aye – 5.

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Ms. Marchal moved that the meeting be adjourned. The motion was seconded by Ms. Huwer and approved by the Board: Aye – 5.

Kevin J. Mitchell, R.Ph., President

Kyle W. Parker, M.B.A., R.Ph., Executive Director

Date: 5-5-14