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Ohio State Board of Pharmacy 77 South High Street, Room 1702 Columbus, Ohio 43215-6126  
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## **Minutes of the September 8-10, 2008** **Meeting of the Ohio State Board of Pharmacy**

### **Monday, September 8, 2008**

10:00 a.m. The Ohio State Board of Pharmacy convened in Room East B, 31<sup>st</sup> Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Nathan S. Lipsyc, R.Ph., *President*; Elizabeth I. Gregg, R.Ph., *Vice-President*; Gregory Braylock, R.Ph.; Donald M. Casar, R.Ph.; Barton G. Kaderly, Public Member; Richard F. Kolezynski, R.Ph.; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

Also present were William T. Winsley, *Executive Director*; Timothy Benedict, *Assistant Executive Director*; William McMillen, *Licensing Administrator*; Mark Keeley, *Legislative Affairs Administrator*; Chris Reed, *Compliance Supervisor*; David Rowland, *Legal Affairs Administrator*; Danna Droz, *Prescription Drug Monitoring Program Director*; and Sally Ann Steuk, *Assistant Attorney General*.

**R-2009-030** Mr. Winsley announced that the following Settlement Agreement with **Hannan Laikos**, R.Ph. (03-3-17097), Wadsworth, Ohio, has been signed by all parties and is now effective.

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

Docket Number D-080709-004

*in the matter of:*

**HANNAN LAIKOS, R.Ph.**

471 Allen Drive  
Wadsworth, Ohio 44281

R.Ph. Number 03-3-17097

This Settlement Agreement is entered into by and between Hannan Laikos 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.

Hannan Laikos 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. Hannan Laikos 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, 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, Hannan Laikos is licensed to practice pharmacy in the State of Ohio.

Whereas, on or about July 8, 2008, pursuant to Chapter 119. of the Ohio Revised Code, Hannan Laikos 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. Hannan Laikos requested a hearing; it was scheduled. The July 8, 2008 Notice of Opportunity for Hearing contains the following allegations or charges:

- (1) Records of the State Board of Pharmacy indicate that Hannan Laikos was originally licensed by the State of Ohio as a pharmacist on August 3, 1987, pursuant to examination, and is currently licensed to practice pharmacy in Ohio.
- (2) Hannan Laikos did, on or about April 10, 2007, misbrand a drug, to wit: when Hannan Laikos received a prescription for 180 doses of Zonegran 25 mg, with directions for use as 3 by mouth two times per day, having 12 refills, Rx #16050445, Hannan Laikos dispensed 120 doses of zonisamide 100 mg, which had not been specifically prescribed by the physician. The patient a 6-year-old child, was subsequently hospitalized. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

Hannan Laikos neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated July 8, 2008; 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, Hannan Laikos knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Hannan Laikos agrees to the imposition of a monetary penalty of two hundred fifty dollars (\$250.00) 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 form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.
- (B) Hannan Laikos must obtain, within one year from the effective date of this Agreement, ten hours of continuing pharmacy education (1.0 CEUs) on preventing medication errors, which may not also be used for license renewal.

Hannan Laikos 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.

Hannan Laikos 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. Hannan Laikos 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.

/s/ Hannan Laikos, R.Ph., Date Signed: 08/25/08  
*Respondent*

/s/ Nathan S. Lipsyc Date Signed: 09/08/08  
*President, Ohio State Board of Pharmacy*

/s/ Sally Ann Steuk Date Signed: 09/08/08  
*Ohio Assistant Attorney General*

10:01 a.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code and to confer with an attorney for the Board regarding pending or imminent court action pursuant to Section 121.22(G)(3) of the Ohio Revised Code. The motion was seconded by Mr. Braylock and a roll-call vote was conducted by President Lipsyc as follows: Braylock – *yes*; Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Kolezynski – *yes*; Lange – *yes*; and Wiesenbahn – *yes*.

11:03 a.m. The Executive Session ended and the meeting was opened to the public.

**R-2009-031** Mr. Braylock moved that the following settlement offer in the matter of **John C. Brungart**, R.Ph. (03-1-11035) Granville, Ohio, be accepted, signed by the President, and become effective immediately. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 7.

**SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY**  
**VOLUNTARY SURRENDER WITH DISCIPLINARY ACTION**  
**PENDING PERMANENT SURRENDER**

Docket Number D-080813-016

*in the matter of:*

**JOHN C. BRUNGART, R.Ph.**  
230 East College Street  
Granville, Ohio 43023

R.Ph. Number 03-1-11035

This Settlement Agreement is entered into by and between John C. Brungart 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.

John C. Brungart enters into this Agreement being fully informed of his rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudication hearing on the issues contained herein.

John C. Brungart is knowingly and voluntarily acknowledging that, in order to settle the disciplinary charges that have been filed by the Board against him and in order to obviate the need to conduct an administrative hearing to consider possible disciplinary sanctions against John C. Brungart's license to practice pharmacy in the State of Ohio, this Agreement is entered into on the basis of the following stipulations, admissions, and understandings:

- (A) The Ohio State Board of Pharmacy is empowered by Section 4729.16 of the Ohio Revised Code to suspend, revoke, place on probation, refuse to grant or renew an identification card, or impose a monetary penalty on the license holder for violation of any of the enumerated grounds.
- (B) John C. Brungart neither admits nor denies the allegations pending in the Board's investigation; however, the Board has initiated and conducted an investigation pursuant to the mandate of Sections 3719.18 and 4729.25 of the Ohio Revised Code.
- (C) John C. Brungart acknowledges that he has been made aware of the investigation and has not failed to cooperate in said investigation. John C. Brungart further acknowledges that he has not been promised or given anything to indicate that the State of Ohio will not proceed with criminal charges; that criminal charges may be or may have been filed pursuant to the discretion of the appropriate prosecuting attorney and/or grand jury. The execution of this agreement does not affect, and is not affected by, any such criminal proceedings.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of a formal hearing at this time, John C. Brungart knowingly and voluntarily **SURRENDERS PERMANENTLY TO THE STATE BOARD OF PHARMACY HIS LICENSE AND REGISTRATION TO PRACTICE PHARMACY, WITH DISCIPLINARY ACTION PENDING, AND IS PRECLUDED FROM MAKING ANY APPLICATION FOR FURTHER REGISTRATION.**

Pursuant to Rule 4729-9-01, John C. Brungart may not be employed by or work in any facility licensed by the Board of Pharmacy to possess or distribute dangerous drugs.

John C. Brungart 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.

John C. Brungart waives any and all claims or causes of action he 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. John C. Brungart waives any rights of appeal pursuant to Chapter 119. of the Ohio Revised Code.

John C. Brungart must return the identification card and license (wall certificate) to the office of the State Board of Pharmacy within ten days after receipt of this Agreement 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.

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.

/s/ John C. Brungart, R.Ph. Date Signed: 08/22/08  
*Respondent*

/s/ Nathan S. Lipsyc Date Signed: 09/08/08  
*President, Ohio State Board of Pharmacy*

/s/ Sally Ann Steuk Date Signed: 09/08/08  
*Ohio Assistant Attorney General*

**R-2009-032** Mrs. Gregg moved that the proposed Cease and Desist order drafted by Board staff be issued in the matter of **Lee Pharmacy Inc.** (02-1237250) Fort Smith, Arkansas. Mr. Kolezynski seconded the motion and it was approved by the Board: *Aye – 7.*

**R-2009-033** Mrs. Gregg moved that the Board accept a settlement offer in the matter of **PSS World Medical, Inc.**, (01-1366350) Louisville, Kentucky, as amended by the Board. The Board's acceptance of a settlement would be contingent on the respondent's agreeing to the changes made by the Board. The motion was seconded by Mr. Kolezynski and approved by the Board: *Aye – 7.*

**R-2009-034** Mr. Winsley and Mr. Rowland presented a proposed process to deal with minor violations of the Board's Continuing Education reporting requirements. The process will involve the issuance of both a Notice of Opportunity For A Hearing and an offer of a settlement without a hearing, thereby allowing the respondent to choose the method of resolution. After discussion, Mrs. Gregg moved that the new process be accepted and approved by the Board. The motion was seconded by Mr. Casar and approved by the Board: *Aye – 6; Nay – 1.*

The Board recessed briefly.

11:13 a.m. Mr. Keeley presented a brief Legislative Report.

**R-2009-035** The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

**University OptionCare**, Columbus, Ohio (02-1543600)  
**Lancaster Hematology/Oncology, Inc.**, Lancaster, Ohio (02-1661700)

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Ms. Lange and approved by the Board: *Aye – 7.*

**R-2009-036** The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

**Triumph Hospital Mansfield**, Mansfield, Ohio (02-1092350)  
**Central Admixture Pharmacy Services**, Valley View, Ohio (02-1312700)

After discussion, Mrs. Gregg moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Wiesenbahn and approved by the Board: *Aye – 7.*

**R-2009-037** The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) received for the following sites:

**Buderer Drug**, Sandusky/ Perrysburg, Ohio (02-1106900) (02-1198400)  
**Fulton County Health Center**, Wauseon, Ohio (02-0037750)

After discussion, Mr. Braylock moved that the Board approve the request as long as the parties to the request comply with the requirements in the rule for such an exemption. The motion was seconded by Mr. Casar and approved by the Board: *Aye* – 7.

**R-2009-038**

The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-11 (Responsible Person) requesting that **Larry Arwood**, R.Ph. (03-3-11911) Columbus, Ohio. be permitted to be the responsible person for the following sites:

<b>Omnicare of Central Ohio</b>	(02-0564600)
<b>Pure Pharmacy Services</b>	(02-1852500)

After discussion, Mr. Braylock moved that the Board approve the request for 120 days. The motion was seconded by Ms. Lange and approved by the Board: *Aye* – 6; *Nay* – 1.

**R-2009-039**

Mr. McMillen presented a request from pharmacy intern **Yulia Bar** (06-0-04981) Powell, Ohio for permission to extend her internship one additional year due to extraordinary circumstances pursuant to Rule 4729-3-04 (Pharmacy Intern Identification Card Renewal). After discussion, Mrs. Gregg moved that Ms. Bar's request be approved, with the stipulation that no further extensions would be granted. The motion was seconded by Mr. Braylock and approved by the Board: *Aye* – 6; *Nay* – 1.

Mr. Braylock reported that the Nursing Board Committee on Prescriptive Governance did not meet last month.

Mr. Benedict gave the Probation Report. There were no issues requiring Board action.

Mr. Benedict said there was no Medical Board Prescribing Committee Report.

Nancy Little, Information Systems Administrator, reported to the Board on the newly implemented eLicensing system.

12:12 p.m. The meeting was recessed for lunch.

1:14 p.m. The Board reconvened with the following members present:

Nathan S. Lipsyc, R.Ph., *President*; Elizabeth I. Gregg, R.Ph., *Vice-President*; Gregory Braylock, R.Ph.; Donald M. Casar, R.Ph.; Bart Kaderly, Public Member; Richard F. Kolezynski, R.Ph.; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

1:14 p.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Mr. Casar and a roll-call vote was conducted by President Lipsyc as follows: Braylock – *yes*; Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Kolezynski – *yes*; Lange – *yes*; and Wiesenbahn – *yes*.

1:41 p.m. The Executive Session ended and the meeting was opened to the public.

1:44 p.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **James R. McManus**, R.Ph. (03-3-14499) Fort Wayne, Indiana.

3:47 p.m. The hearing ended and the record was closed.

3:49 p.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Mr. Casar and a roll-call vote was conducted by

President Lipsyc as follows: Braylock – *yes*; Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Kolezynski – *yes*; Lange – *yes*; and Wiesenhahn – *yes*.

4:25 p.m. The Executive Session ended and the meeting was opened to the public.

**R-2009-040** After votes were taken in public session, the Board adopted the following order in the matter of **James R. McManus**, R.Ph. (03-3-14499) Fort Wayne, Indiana.

**ORDER OF THE STATE BOARD OF PHARMACY**

Docket Number D-080110-031

*in the matter of:*

**JAMES. R. MCMANUS, R.Ph.**

6500 Saint Joe Road  
Fort Wayne, Indiana 46835

R.Ph. Number 03-3-14499

**INTRODUCTION**

The matter of James R. McManus came for hearing on September 8, 2008, before the following members of the Board: Nathan S. Lipsyc, R.Ph. (*presiding*); Gregory Braylock, R.Ph.; Donald M. Casar, R.Ph.; Elizabeth I. Gregg, R.Ph.; Barton G. Kaderly, Public Member; Richard F. Kolezynski, R.Ph.; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

James R. McManus was not represented by counsel. The state of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

**SUMMARY OF EVIDENCE**

State's Witnesses: Todd Knauss, Ohio State Board of Pharmacy  
James R. McManus, Respondent

Respondent's Witness: Mary A. Rush

State's Exhibits:

1. Copy of Summary Suspension/Notice of Opportunity For Hearing letter [01-10-08]
- 1A-1C. Procedurals
2. Ohio State Board of Pharmacy Pharmacist Renewal Application for James R. McManus [09-15-07 to 09-15-08]
3. News - Post-Tribune (Northwest Indiana) Article [08-23-06]
4. Judgment, United States of America v. James Roy McManus, Case No. 3:06cr0113AS, United States District Court Northern District of Indiana [06-29-07]
5. Affidavit, State of Indiana County of St Joseph by Ryan E. Moore [08-18-06]
6. Criminal Complaint, Commonwealth of Pennsylvania vs. James R. McManus, Case No. CP-03-CR-336-2005, Court of Common Pleas of Armstrong County [04-14-05]
7. Criminal Docket, Commonwealth of Pennsylvania v. James R. McManus, Case No. CP-03-CR-0000337-2005, Court of Common Pleas of Armstrong County [04-14-05]; Affidavit of Probable Cause; Order for Accelerated Rehabilitative Disposition Program [07-07-05]
8. Letter from Indiana Board of Pharmacy to James McManus [08-20-08]

Respondent's Exhibits:

- A. Letter from James R. McManus, R.Ph. [09-08-08]
- B. Letter from Hani Ahmad, M.D.; Letter from Ruth A. Bracht, LCSW [08-15-08]; Family & Children's Services Therapy Session Charges for James McManus [06-24-08 to 08-25-08]; Letter from James Burg, Ph.D. To Whom It May Concern [08-14-08]
- C. Letter from Angel Schnick [08-22-08]; Letter from Amanda Miller, U.S. Probation Officer [08-28-08]
- D-E. Nine Letters of Support [08-20-07 to 09-07-08]
- F. Internet Safety Plan [not dated]
- G. Resume of James R. McManus, PharmD [not dated]
- H. List of Continuing Pharmaceutical Education Credits [2006-2008]

**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 State Board of Pharmacy indicate that James R. McManus was originally licensed by the State of Ohio as a pharmacist on March 5, 1982, by examination, and is currently licensed to practice pharmacy in Ohio.
- (2) James R. McManus was, on or about June 29, 2007, convicted in the United States District Court, Northern District of Indiana, South Bend Division, of Transfer of Obscene Materials to [a minor] in violation of Title 18 U.S.C. Section 1470, a felony. James R. McManus was sentenced to 15 months incarceration in federal prison followed by 2 years probation United States vs. James McManus, 3:06 CR 0113AS.
- (3) James R. McManus was, on or about July 7, 2005, placed in a diversion program in the Common Pleas Court of Armstrong County, Pennsylvania, for Open Lewdness and Disorderly Conduct. Pennsylvania vs. McManus, CP-03-CR-336-2005. This court action was for an act committed on April 14, 2005.
- (4) James R. McManus was, on or about July 7, 2005, placed in a diversion program in the Common Pleas Court of Armstrong County, Pennsylvania, for Indecent Exposure and Disorderly Conduct. Pennsylvania vs. McManus, CP-03-CR-337-2005. This court action was for an act committed on February 14, 2005.

**CONCLUSIONS OF LAW**

The State Board of Pharmacy concludes that paragraphs (2) through (4) 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.

**DECISION OF THE BOARD**

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby suspends indefinitely the pharmacist identification card, No. 03-3-14499, held by James R. McManus and such suspension is effective as of the date of the mailing of this Order.

- (A) James R. McManus, pursuant to Rule 4729-9-01(F) of the Ohio Administrative Code, may not be employed by or work in a facility licensed by



the State Board of Pharmacy to possess or distribute dangerous drugs during such period of suspension.

- (B) James R. McManus, 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.

Further, after five years from the effective date of this Order, the Board will consider any petition filed by James R. McManus for a hearing, pursuant to Ohio Revised Code Chapter 119., for reinstatement. The Board will only consider reinstatement of the license to practice pharmacy in Ohio if the following conditions have been met:

- (1) James R. McManus must have submitted to the Board within 90 days from this date of this Order a full psychiatric evaluation and treatment plan. Upon reappearance James R. McManus must show compliance with his treatment plan and provide a letter from his health care provider showing compliance and potential ability to deal with stresses and triggers of work environment.
- (2) Compliance with the continuing pharmacy education requirements set forth in Chapter 4729-7 of the Ohio Administrative Code as applicable and in effect on the date of petitioning the Board for reinstatement;
- (3) Compliance with the terms of this Order.

Upon such time as the Board may consider reinstatement, James R. McManus will be afforded a Chapter 119. hearing. At such time, the Board may consider reinstatement with or without restrictions and/or conditions as the Board deems appropriate under the circumstances.

Elizabeth Gregg moved for Findings of Fact; Richard Kolezynski seconded the motion. Motion passed (Aye-7/Nay-0).

Elizabeth Gregg moved for Conclusions of Law; Jerome Wiesenhahn seconded the motion. Motion passed (Aye-7/Nay-0).

Gregory Braylock moved for Action of the Board; Donald Casar seconded the motion. Motion passed (Aye-7/Nay-0).

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4:32 p.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Gregory Thomas Fisher**, R.Ph. (03-2-21259) Washington Township, Ohio.

5:10 p.m. The hearing was suspended and Mr. Braylock moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Ms. Lange and a roll-call vote was conducted by President Lipsyc as follows: Braylock – *yes*; Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Kolezynski – *yes*; Lange – *yes*; and Wiesenhahn – *yes*. The Executive Session ended and the meeting was opened to the public.

**R-2009-041**

Ms. Lange moved that the hearing in the matter of **Gregory Thomas Fisher**, R.Ph. (03-2-21259) Washington Township, Ohio be continued until Mr. Fisher could show strict compliance with his August 8, 2007 Board order and that the earliest time Mr. Fisher could reappear before the Board would be at the March 2009 meeting. The motion was seconded by Mrs. Gregg and approved by the Board: *Aye* – 7.

5:30 p.m. The meeting was recessed for the day.

## **Tuesday, September 9, 2008**

8:18 a.m. The Ohio State Board of Pharmacy convened in Room East B, 31<sup>st</sup> Floor, of the Vern Riffe Center for Government and the Arts, 77 South High Street, Columbus, Ohio, with the following members present:

Nathan S. Lipsyc, R.Ph., *President*; Elizabeth I. Gregg, R.Ph., *Vice-President*; Donald M. Casar, R.Ph.; Barton G. Kaderly, Public Member; Jerome J. Wiesenhahn, R.Ph.; and Deborah A. Lange, R.Ph.

**R-2009-042** After discussion, Mrs. Gregg moved that the Board minutes of August 4-6, 2008, be approved as amended. Mr. Casar seconded the motion and it was approved by the Board: *Aye* – 5.

8:37 a.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to create a record in accordance with Ohio Revised Code Chapters 119. and 4729. in the matter of **Lisa Marie Pawliski**, R.Ph., (03-1-19015) Monclova, Ohio.

8:57 a.m. The record was closed. The Board recessed briefly.

9:10 a.m. The Board was joined by Assistant Attorney General Sally Ann Steuk to conduct an adjudication hearing in accordance with the Ohio Revised Code Chapters 119. and 4729. in the matter of **Dianne Marie Boes**, R.Ph. (03-2-18183) Marion, Ohio.

11:27 a.m. The hearing ended and the record was closed.

11:28 a.m. Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Ms. Lange and a roll-call vote was conducted by President Lipsyc as follows: Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Wiesenhahn – *yes*; and Lange – *yes*.

12:00 p.m. The Executive Session ended and the meeting was opened to the public.

12:02 p.m.  
**R-2009-043** After votes were taken in public session, the Board adopted the following order in the matter of **Dianne Marie Boes**, R.Ph. (03-2-18183) Marion, Ohio.

### **ORDER OF THE STATE BOARD OF PHARMACY**

Docket Number D-071204-021

*in the matter of:*

**DIANNE MARIE BOES, R.Ph.**

1670 Union Park Circle  
Marion, Ohio 43302

R.Ph. Number 03-2-18183

### **INTRODUCTION**

The matter of Dianne Marie Boes came for hearing on September 9, 2008, before the following members of the Board: Nathan S. Lipsyc, R.Ph. (*presiding*); Donald M. Casar, R.Ph.; Elizabeth I. Gregg, R.Ph.; Barton G. Kaderly, Public Member; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

Dianne Marie Boes was represented by Daniel D. Connor. The state of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

### **SUMMARY OF EVIDENCE**

State's Witness: Paul Kover, Ohio State Board of Pharmacy

Respondent's Witness: Dianne Marie Boes, R.Ph, Respondent  
Gregory Candel  
Michelle Lee Stricklen, R.Ph.

#### State's Exhibits:

1. Copy of Summary Suspension/Notice of Opportunity For Hearing letter [12-4-07]
- 1A-1E. Procedurals
2. Copy of Notarized Statement of Thomas P. Alig of IVC Healthcare [05-29-07]; Statement of Dianne Flowers [05-09-07]
3. Notarized Statement of Hal E. Augsberger [05-24-07]
4. Notarized Statement of Zachary Tressel [05-16-07]
5. Notarized Statement of Tricia M. Savage [05-16-07]

#### Respondent's Exhibits:

- A. Talbot Hall Medical Records [05-24-07 to 07-24-07]
- B. Dr. Eric M. Stemmer Medical Records [06-27-04] to 07-15-08]
- C. Journey Offender Services, LLC Assessment [08-23-08]
- D. Letter from Mark C. Brown to Daniel D. Connor [08-12-08]; Letter from Mark C. Brown to Dr. Eric Stemmer [02-12-08]
- E. Letter from M. Karen Kegelmeyer to Daniel D. Connor [08-01-08]
- F. Drug Screen Test Results [06-07-07 to 07-17-07]
- G. Letter from Michelle Stricklen to State Board of Pharmacy [08-12-08]
- H. Five Letters of Support [08-06-08 to 08-21-08]

### **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 State Board of Pharmacy indicate that Dianne Marie Boes was originally licensed by the State of Ohio as a pharmacist on February 23, 1990, by examination, and is currently licensed to practice pharmacy in Ohio.
- (2) Dianne Marie Boes did, from December 1, 2006, through May 9, 2007, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of Triumph Hospital, beyond the express or implied consent of the owner, to wit: Dianne Marie Boes admittedly stole hydrocodone/APAP 5/500 mg with acetaminophen 500 mg, a schedule III controlled substance, from her employer. Audits show a shortage of this drug of 1,131 tablets. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.
- (3) Dianne Marie Boes did, on or about May 8, 2007, with purpose to deprive, knowingly obtain or exert control over dangerous drugs, the property of MBR Pharmacy, beyond the express or implied consent of the owner, to wit: Dianne Marie Boes admittedly stole 9 unit does of hydrocodone 10 mg with acetaminophen 325 mg, a schedule III controlled substance, from her employer. Such conduct is in violation of Section 2913.02 of the Ohio Revised Code.

## CONCLUSIONS OF LAW

- (1) The State Board of Pharmacy concludes that paragraphs (2) and (3) 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 (2) and (3) 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.

## DECISION OF THE BOARD

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby places on probation for five years the pharmacist identification card, No. 03-2-18183, held by Dianne Marie Boes effective as of the date of the mailing of this Order. The terms of probation are as follows:

- (A) Dianne Marie Boes must enter into a **new** contract, signed within ninety days from the effective date of this Order, with an Ohio Department of Alcohol and Drug Addiction Services (ODADAS) treatment provider or a treatment provider acceptable to the Board for a period of not less than five years and submit a copy of the signed contract to the Board office with the renewal application. The contract must provide that:
  - (1) **Random, observed** urine drug screens shall be conducted at least once each month for the first year and then at least once every three months for the remaining four years.
    - (a) 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.
    - (b) 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.
  - (2) The intervener/sponsor shall submit to the Board reports, 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.
  - (3) The program shall immediately report to the Board any violations of the contract and/or lack of cooperation.
- (B) Dianne Marie Boes must submit quarterly progress reports to the Board (due January 10, April 10, July 10, and October 10 of each year of probation).
- (C) Dianne Marie Boes must continue with cognitive behavioral therapy and her health care provider must provide quarterly progress reports to the Board on her condition and her progress for the period of her probation.
- (D) Other terms of probation are:

- (1) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.
  - (2) Dianne Marie Boes must not violate the drug laws of Ohio, any other state, or the federal government.
  - (3) Dianne Marie Boes must abide by the rules of the State Board of Pharmacy.
  - (4) Dianne Marie Boes must comply with the terms of this Order.
  - (5) Dianne Marie Boes' license is deemed to be not in good standing until successful completion of the probationary period.
- (E) Any violation of probation may result in a Board hearing to consider alternative or additional sanctions under Section 4729.16 of the Ohio Revised Code.

Dianne Marie Boes 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.

Elizabeth I. Gregg moved for Findings of Fact; Jerome J. Wiesenhahn seconded the motion. Motion passed (*Aye-5/Nay-0*).

Elizabeth I. Gregg moved for Conclusions of Law; Jerome J. Wiesenhahn seconded the motion. Motion passed (*Aye-5/Nay-0*).

Donald Casar moved for Action of the Board; Barton Kaderly seconded the motion. Motion passed (*Aye-5/Nay-0*).

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12:03 p.m. The Board recessed for lunch.

1:18 p.m. The Board reconvened with the following members present:

Nathan S. Lipsyc, R.Ph., *President*; Elizabeth I. Gregg, R.Ph., *Vice-President*; Donald M. Casar, R.Ph.; Barton G. Kaderly, Public Member; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

Mrs. Gregg moved that the Board go into Executive Session for the purpose of the investigation of complaints regarding licensees and registrants pursuant to Section 121.22(G)(1) of the Ohio Revised Code. The motion was seconded by Ms. Lange and a roll-call vote was conducted by President Lipsyc as follows: Casar – *yes*; Gregg – *yes*; Kaderly – *yes*; Wiesenhahn – *yes*; and Lange – *yes*.

1:34 p.m. The Executive Session ended and the meeting was opened to the public.

**R-2009-044** Mrs. Gregg moved that the Board summarily suspend the license to practice pharmacy belonging to **Christy T. Stricker**, R.Ph. (03-3-11706) Granville, Ohio, pursuant to Ohio Revised Code 3719.121 (A) and (B). Ms. Lange seconded the motion and it was approved by the Board: *Aye* – 5.

**R-2009-045** After votes were taken in public session, the Board adopted the following order in the matter of **Lisa Marie Pawliski**, R.Ph., (03-1-19015) Monclova, Ohio.

**ORDER OF THE STATE BOARD OF PHARMACY**

Docket Number D-080709-002

*in the matter of:*

**LISA MARIE PAWLISKI, R.Ph.**

3455 Weckerly Road  
Monclova, Ohio 43542

R.Ph. Number 03-1-19015

**INTRODUCTION**

The matter of Lisa Marie Pawliski came for consideration on September 9, 2008, before the following members of the Board: Nathan S. Lipsyc, R.Ph. (*presiding*); Donald M. Casar, R.Ph.; Elizabeth I. Gregg, R.Ph.; Barton G. Kaderly, Public Member; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

Lisa Marie Pawliski was not present nor was she represented by counsel. The State of Ohio was represented by Sally Ann Steuk, Assistant Attorney General.

**SUMMARY OF EVIDENCE**

State's Witness: Paul Kover, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses: None

State's Exhibits:

1. Notice of Opportunity for Hearing Letter [07-09-08]  
1A-1B. Procedurals
2. Letter from Lisa Pawliski to Mr. Winsley [08-07-08]
3. Formula Worksheet at Buderer Drug Co. for Trichloroacetic Acid Lot T604180 [08-14-06]
4. Formula Worksheet at Buderer Drug Co. for Trichloroacetic Acid Lot T605021 [12-05-06]
5. Report of Analytical Services for Trichloroacetic Acid Lots T604180 and T605021 [03-16-07]
6. Dangerous Drug Distributor Inspection Report for Buderer Drug Inc. [01-06-08]; Response Letter from Matthew J. Buderer, to William Winsley with attachments [02-01-08]

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 State Board of Pharmacy finds the following to be fact:

- (1) On July 9, 2008, Lisa Marie Pawliski was notified by letter of her right to a hearing, her rights in such hearing, and her right to submit any contentions in writing.
- (2) As demonstrated by return receipt dated July 15, 2008, Lisa Marie Pawliski received the letter of July 9, 2008, informing her of the allegations against her, and her rights.

- (3) Lisa Marie Pawliski has submitted her contentions in writing by letter dated August 7, 2008, but has not requested a hearing in this matter, therefore the matter was referred to the Board for consideration.
- (4) Records of the State Board of Pharmacy indicate that Lisa Marie Pawliski was originally licensed by the State of Ohio as a pharmacist on July 29, 1991, by examination, and is currently licensed to practice pharmacy in Ohio.
- (5) Lisa Marie Pawliski did, on or about August 15, 2006, misbrand a drug, to wit: when Lisa Marie Pawliski received an order for trichloroacetic acid (TCA) with a concentration of 30%, Lot #T604180 RR, she labeled it correctly yet dispensed trichloroacetic acid (TCA) with a concentration of 48%, which had not been specifically ordered by the physician. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.
- (6) Lisa Marie Pawliski did, on or about December 6, 2006, misbrand a drug, to wit: when Lisa Marie Pawliski received an order for trichloroacetic acid (TCA) with a concentration of 30%, Lot #T605021 KK-LL, she labeled it correctly yet dispensed trichloroacetic acid (TCA) with a concentration of 50%, which had not been specifically ordered by the physician. Three patients were subsequently harmed. Such conduct is in violation of Section 3715.52(A)(2) of the Ohio Revised Code.

#### **CONCLUSIONS OF LAW**

The State Board of Pharmacy concludes that paragraphs (5) and (6) of the Findings of Fact constitute being guilty of unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.

#### **DECISION OF THE BOARD**

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby adjudicates the matter of Lisa Marie Pawliski as follows:

- (A) On the basis of the Findings of Fact and Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes on Lisa Marie Pawliski a monetary penalty of two hundred fifty dollars (\$250.00) due and owing within thirty days of the issuance of this Order. The monetary penalty 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.
- (B) Lisa Marie Pawliski must obtain, within six months from the effective date of this Order, five (0.5 CEUs) of approved continuing pharmacy education in medication error prevention, which may not also be used for license renewal.

Elizabeth I. Gregg moved for Findings of Fact; Donald Casar seconded the motion. Motion passed (*Aye-5/Nay-0*).

Elizabeth I. Gregg moved for Conclusions of Law; Jerome J. Wiesenbahn seconded the motion. Motion passed (*Aye-5/Nay-0*).

Elizabeth I. Gregg moved for Action of the Board; Jerome J. Wiesenbahn seconded the motion. Motion passed (*Aye-5/Nay-0*).

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**R-2009-046** The following candidates for licensure by reciprocity met with members of the Board in Room South A, 31<sup>st</sup> Floor of the Vern Riffe Center. The candidates introduced themselves to the Board, and then participated in a discussion of pharmacy laws and rules with Mr. McMillen.

Nancy Adomako	<i>Illinois</i>	Martin John Menard	<i>Michigan</i>
Nathan Ryan Ash	<i>Indiana</i>	Carmen Anubis Morales	<i>Washington</i>
David Stanley Askew	<i>Massachusetts</i>	Grace S. Murad	<i>Michigan</i>
Philecia Chavers Avery	<i>Tennessee</i>	Barbara Anne Szymusiak Mutnick	<i>Michigan</i>
Alan Edward Bilbrey	<i>Nevada</i>	Muralikrishna Narra	<i>Vermont</i>
Karen Alice Clemency	<i>New York</i>	Imtiyaz A. Patel	<i>Illinois</i>
Tina Gail Dicuccio	<i>Pennsylvania</i>	Johanna Quinn Plunkett	<i>South Carolina</i>
Maria C. Escobedo	<i>Illinois</i>	Andrea Lisa Roberts	<i>New York</i>
Rebecca Brooks Goad	<i>West Virginia</i>	Mohammed Majeed Siddiqui	<i>Illinois</i>
Summer A. Hafiz	<i>Washington</i>	Jeremy Joseph Taylor	<i>West Virginia</i>
Anil Raja Karnati	<i>Maryland</i>	Rebecca Ann Taylor	<i>Pennsylvania</i>
Simon Waihon Lam	<i>New Jersey</i>	Connie L. Thomas	<i>Indiana</i>
Sandra Ivette Landers	<i>Georgia</i>	Peinie Penny Young	<i>California</i>

2:00 p.m.

**R-2009-047** Mr. Benedict and Mr. Reed discussed the results of a field staff policy review with the Board. Mrs. Gregg moved that the changes be approved as presented. The motion was seconded by Mr. Casar and approved by the Board: *Aye* – 5.

**R-2009-048**

#### **BARRICADE INSPECTION REPORTS [As adopted September 9, 2008]**

All barricade inspection reports will be made only on a Prescription Room Barricade Inspection Report (Form PHA-0611).

All barricade inspection reports, including those inspections that result in the approval or disapproval of a barricade, will be completed and attached to the Dangerous Drug Distributor Inspection Report (Form PHA 0610).

A previously approved barricade must be inspected each time the location is given a "full" inspection. The inspection is to ensure that the barricade still complies with Board of Pharmacy regulations. The Dangerous Drug Distributor Inspection Report must indicate that such an inspection was conducted and that a barricade inspection report is attached indicating the barricade is approved or disapproved.

Any barricade that is moved, modified, or changed in any manner must be re-inspected and approved by an agent of the Board of Pharmacy prior to its authorization for use.

**R-2009-049**

#### **BOARD EMPLOYEE BADGE [As adopted September 9, 2008]**

No badge, other than that supplied by the Board, may be possessed by a Board employee when involved in official Board business.

No badge may be displayed by a Board employee while on the premises of any registrant of the Board of Pharmacy, while interviewing any health care professional, or while interviewing any employee of a registrant. Registrant, in this instance, includes a pharmacy intern, pharmacist, or pharmacy.

Board-issued badges may be displayed when the employee is involved in official Board business under the following circumstances: while in court buildings or police depart-



ments, to police officers, and during the execution of search warrants at places other than the premises of a registrant.

At the end of service with the Board of Pharmacy, all badges of Board members and/or staff will be surrendered to the Board.

Any alleged violation of this Board Policy or any loss of a badge shall be immediately reported to the Executive Director or designee.

**R-2009-050**

**POLICY REGARDING BOARD EMPLOYEES GIVING  
TESTIMONY IN CIVIL MATTERS  
[As adopted September 9, 2008]**

Employees of the Board of Pharmacy are prohibited from giving testimony in civil matters when such testimony relates to functions or duties attendant to the employee's Board position, or relate to abilities or qualifications attained as a result of employment with the Board, unless the following criteria are met:

- (1) A subpoena is received,
- (2) The employee's supervisor is notified in advance of testifying,
- (3) The Legal Affairs Administrator is notified of receipt of the subpoena, and the date, time, and location of the court appearance,
- (4) The Legal Affairs Administrator is present when testimony is given at any proceeding other than in a court appearance such as depositions, interrogatories, etc. Depositions, interrogatories, et cetera must be reviewed by the Legal Affairs Administrator after transcription but prior to final submission as is provided by law,
- (5) Witness fee of \$400.00 (\$750.00 for employees having degrees in pharmacy or law) per half-day plus expenses are tendered in advance of giving testimony (which are, according to law, placed into the State's general revenue fund); check must be made payable to the Treasurer – State of Ohio. This fee is not to be charged when a governmental agency is the party requesting testimony,
- (6) Content of expected testimony must be reviewed with the employee's supervisor prior to the giving of such testimony, and in the case of giving of testimony by an employee pharmacist, the expected testimony must be reviewed with the Executive Director or designee.

As used in this policy, "civil matters" include, but are not limited to, court appearances, trials, pretrial hearings, depositions, and interrogatories.

**R-2009-051**

**DISCUSSION OF CONFIDENTIAL MATERIAL  
[As adopted September 9, 2008]**

Confidential information relating to investigations, grand jury proceedings, court proceedings, and similar confidential information will not be discussed with individuals or companies not immediately involved in a cooperative effort with the Board in the activity relating to that matter.

**R-2009-052**

**FIELD STAFF REPORT  
[As adopted September 9, 2008]**

All Field Staff Reports (Daily Activity Reports) shall be computer-generated and manually signed and dated by the employee. Reports must be submitted weekly to the Board office.

**R-2009-053**

**DESTRUCTION OF RETURNED CONTROLLED  
SUBSTANCES FROM HOSPICE PATIENTS  
[As adopted September 9, 2008]**

- (A) Currently, the Board of Pharmacy grants authorization to destroy controlled substances to the following:
- (1) Hospitals/Clinics to destroy outdated or adulterated controlled substances from its stock.
  - (2) Pharmacies that service other institutions (i.e., nursing homes); these controlled substances may be destroyed at the nursing home or returned to the pharmacy for destruction.
  - (3) District managers of chain pharmacies.
  - (4) One-time authorization, upon written request, from terminal distributors.
- (B) Requests have been made from pharmacies dispensing controlled substances to hospice patients to allow for the return of the unused controlled substances to the pharmacy by the hospice nurse and the destruction of these substances at the pharmacy.
- (C) The following procedure will be followed to allow for the return and destruction of these controlled substances:
- (1) The responsible pharmacist at the terminal distributor location (pharmacy) will submit to the Board, in writing, a request for authorization for destruction for hospice prescriptions and include the name of the pharmacy, name of the hospice, and the names of all pharmacists authorized by the responsible pharmacist to destroy the drugs.
  - (2) Upon receipt of written authorization from the Board, the pharmacist will document the following procedure and submit this documentation to the Board office:
    - (a) An exact inventory will be taken of all controlled substances at the patient's home by the nurse from the hospice and a family member. This inventory will be written, signed, and dated by both the nurse and the family member assisting in the count. This list will also contain the name of the patient for whom the controlled substance(s) was dispensed and the prescription number(s).
    - (b) A copy of this inventory will be left with the family member by the hospice nurse.
    - (c) The hospice nurse will personally return these controlled substances to the dispensing pharmacy which has obtained permission to destroy. The return of these controlled substances will take place as soon as possible, but must be returned within one working day.

- (d) Upon return to the pharmacy, the pharmacist and the hospice nurse shall immediately re-inventory the controlled substances. At the completion of the inventory, the pharmacist and the hospice nurse shall destroy the returned controlled substances. This inventory and the actual destruction will be signed and dated by the pharmacist and the hospice nurse, and indicate the method of destruction. This documentation will also include the name of the patient, prescription number(s) for the controlled substance(s) destroyed, and the name and terminal distributor license number of the pharmacy.
- (e) The pharmacist shall maintain, for a period of three years, the documentation received from the hospice nurse for the removal of the controlled substances from the patient's home and the original documentation of the re-inventory and destruction of the controlled substances. These destruction records must be maintained separately from all other required records in the pharmacy.
- (f) A copy of both documents shall be forwarded to the Board office.

**R-2009-054**

**DESTRUCTION OF CONTROLLED SUBSTANCES BY NURSING HOME PROVIDERS  
[As adopted September 9, 2008]**

After determination by the Executive Director that all requirements have been met, the Executive Director shall forward the following authorization letter:

[Date]

[NAME OF PHARMACY]

[Address]

[City, State, Zip]      Attn: [Name of R.Ph.]

Dear Pharmacist:

Under authority granted by paragraph (B)(4) of Rule 4729-9-06 of the Ohio Administrative Code, this letter authorizes [NAME OF PHARMACY], terminal distributor license number 02-[#####], to dispose of dangerous drugs that are controlled substances from the following locations:

<u>HEALTH CARE FACILITY NAME</u>	<u>LICENSE NUMBER</u>
[NAME OF FACILITY]	[LICENSE NUMBER]

The following pharmacist(s) are authorized to destroy controlled substances:

<u>PHARMACIST NAME</u>	<u>LICENSE NUMBER</u>
[NAME OF PHARMACIST]	[LICENSE NUMBER]

This is in accordance with the provisions of paragraph (C) of Rule 4729-9-06 of the Ohio Administrative Code on the condition that one of the two procedures listed below be followed:

- (1) Procedure for destruction at the health care facility:
  - (a) An Ohio registered pharmacist, whose license is active and in-good-standing and whose name(s) has been submitted to be an authorized pharmacist, personally destroys the unwanted controlled substances at the licensed location wherein they are stored and in the presence of the nurse from the health care facility.

- (b) A record is made in triplicate, recording in detail, the drugs destroyed. It shall be signed by the registered pharmacist destroying the drugs and the nurse witnessing the destruction of such drugs.
  - (c) The form shall identify by name and the terminal distributor license number of the location of the drug destruction, the persons destroying the drugs, name and strength of the drugs destroyed, quantity of drugs destroyed, and indication by patient name or prescription number to whom the drug had been originally dispensed. If the unwanted drugs have not been dispensed to a patient, the report shall indicate the source of the drugs which are being destroyed (i.e., emergency kit or contingency kit). The report shall also record the method of the drug destruction.
  - (d) The original copy of the form is retained at the health care facility.
  - (e) The second copy is retained at the pharmacy supplying the drugs to the health care facility, and is kept with other records of accountability for controlled substances.
  - (f) The third copy is forwarded to the State Board of Pharmacy within thirty (30) days following destruction of the drugs.
- (2) Procedure for the return of the controlled drugs to the pharmacy for destruction at the pharmacy or another site.
- (a) A record of the controlled drugs to be returned to the pharmacy shall be prepared. This record shall include the drug name, strength, dosage form and quantity, the name of the patient and the prescription number if applicable, the name and pharmacy's terminal distributor of dangerous drug license number for the health care facility. This record shall be signed and dated by the nurse. One copy shall be forwarded to the pharmacy and one copy shall be retained at the health care facility.
  - (b) An Ohio registered pharmacist, whose license is active and in good standing, and whose name has been submitted to be an authorized pharmacist to destroy the controlled drugs shall review the record and arrange for pick up of the drugs. A system shall be required that will show the controlled drugs were picked up at the health care facility and that the drugs were received in the pharmacy.
  - (c) The drugs shall be prepared by the health care facility for return to the pharmacy in a sealed, tamper-evident container. Upon receipt, a pharmacist shall verify in writing that all the controlled drugs were returned, and sign and date the copy of the record.
  - (d) Returned controlled drugs from a health care facility must be stored in a secure area in the pharmacy, apart from the storage of drugs used for dispensing, and must be destroyed within forty-five (45) days of return.
  - (e) When the drugs are actually destroyed, a record shall be made which shall include all of the information required in paragraph (2)(a). This record shall be dated and signed by both the registered pharmacist destroying the drugs and another registered pharmacist, employed by the pharmacy, witnessing the destruction of such drugs. The method of destruction shall be included on the record. The record shall also show, if the drugs are destroyed at a location other than the pharmacy, the name and address of the site of destruction.
  - (f) The original copies of the returned, destroyed controlled-drug records are to be retained at the pharmacy with other records of accountability for controlled substances.

(g) A copy of these records of the returned, destroyed controlled drugs must be forwarded to the State Board of Pharmacy within thirty (30) days following the actual destruction of the drugs.

Federal regulations do not allow for the return and reuse of controlled substances that have been dispensed pursuant to a prescription or transferred to a location that is not licensed by the federal Drug Enforcement Administration.

It is understood that if any other nursing home is added to the aforementioned list of [NAME OF PHARMACY], or no longer is associated with any of the above, [NAME OF PHARMACY] shall immediately notify the Ohio State Board of Pharmacy in writing of such change, in order that its records may be corrected.

It is understood that if any pharmacist whose name was submitted on the request for destruction is no longer employed or authorized by [NAME OF PHARMACY] to destroy controlled substances that [NAME OF PHARMACY] shall immediately notify the Ohio State Board of Pharmacy in writing of such change, in order that its records may be corrected.

It is understood that if any pharmacist is employed by [NAME OF PHARMACY] after the request for destruction was submitted, [NAME OF PHARMACY] shall immediately notify the Ohio State Board of Pharmacy in writing of such addition, in order that its records may be corrected.

This authorization is valid for one year from the date of this letter provided that all conditions as stated in your request remain the same or that the Board is immediately notified of any change. If you wish further authorization you must make that request in writing within one year from this date.

**R-2009-055**

**DESTRUCTION OF DRUGS  
[As adopted September 9, 2008]**

**Dangerous Drugs**

Destruction of dangerous drugs, which are not controlled substances, will not be the responsibility of the Board of Pharmacy except under unusual circumstances. Those unusual circumstances will be given prior authorization by the Board's supervisory staff. The destruction of dangerous drugs will be documented in a report of investigation utilizing an investigation case number assigned by the Board office.

**Controlled Substances**

Destruction of controlled substances will be made only by documentation on a DEA Form 41 (Registrants Inventory of Drugs Surrendered). There will be no alteration of this form during its use or deviation from the instructions on the form.

Only under special circumstances will controlled substances be removed from the licensed location for destruction. Those special circumstances must be approved by the Board's supervisory staff.

When a destruction is made at a non-licensed location, it shall be documented with DEA Form 41 and a Report of the Investigation utilizing an investigation case number assigned by the Board office. When a destruction is made at a licensed location, it shall be documented with DEA Form 41.

When a destruction is recorded on a DEA Form 41 and corrections are made, they shall be made by dating and initialing the correction. That correction, dating, and initialing shall be made in a legible manner so that it is obvious what correction has been made. No DEA Form 41 shall be executed unless it is legible.

When a destruction is conducted that involves the Board, all drugs requested to be destroyed shall be destroyed except for special circumstances as noted above.

All field employees of the Board of Pharmacy shall carry with them blank copies of DEA Form 41 while working for the Board of Pharmacy.

**R-2009-056**

**EVIDENCE HANDLING  
[As adopted September 9, 2008]**

All evidence collected and in the possession of a Board employee must be reported pursuant to a case number and a written report.

All drug evidence in the possession of the Board employee will be brought to the main office in Columbus at the earliest possible time and placed into the Board of Pharmacy's evidence control system, unless they are being retained in the custody of a law enforcement agency.

In instances when evidence may be split between a law enforcement agency and the Board of Pharmacy (such as when controlled substances are retained by a police department for criminal prosecution, and misbranded or adulterated drugs are retained by the Board of Pharmacy for administrative action), the drugs in possession of the Board will be placed into the evidence control system.

All drug evidence will be submitted to the offices of the Ohio Board of Pharmacy at the earliest possible time, unless verbal approval is given by the Compliance Supervisor or the Assistant Executive Director.

If only documents are collected in an investigation that will result in a criminal prosecution and/or administrative action, the items of evidence can be either retained in the personal custody of the Board employee or submitted to the Board's evidence control system at the discretion of the employee.

**R-2009-057**

**BOARD OF PHARMACY DRUG LAW ENFORCEMENT FUND  
[As adopted September 9, 2008]**

**GOAL:**

Section 4729.65 of the Ohio Revised Code, as amended by Sub. H.B. 266 by the 118th General Assembly, provides that the Board maintain and utilize a special fund designated as "The Board of Pharmacy Drug Law Enforcement Fund." This law further states that such money shall be used solely to subsidize the drug law enforcement efforts of the Board. Thus, Board costs associated with drug law enforcement activities conducted under Chapters 2925., 3715., 3719., and 4729. of the Revised Code may be subsidized by this fund. Activities excluded from receiving such funds are administrative matters such as those related to licensing and salaries. Activities which may be subsidized include, but are not limited to: the purchase of technical equipment, supplies, reference texts, publications, and training of personnel specifically related to drug law enforcement.

**SPENDING OF FUNDS:**

As additional funds are deposited into the account, further requests for spending authority shall be instituted as required by the Assistant Executive Director. Once spending authority has been obtained from the Controlling Board, purchase requests shall be initiated in writing by the Board's Compliance Supervisor.

Requests shall specify the equipment, supplies and/or services for which funds are requested to be spent and the reasons(s) for the request. Such requests shall be directly

forwarded to the Assistant Executive Director and the Legal Affairs Administrator. The request will be reviewed for propriety as set forth in the goals of this policy, for compliance with state and federal guidelines for spending, and for availability and advisability of spending of such funds. Such request shall then be forwarded to the Executive Director of the Board for final approval. If denied, the request ceases.

If additional spending authority is needed, the Assistant Executive Director shall appear before the Controlling Board when the request is considered to answer any questions. Once spending authority has been obtained, the Fiscal Officer shall prepare the required documents to expend the funds requested; such money shall then be spent by the Compliance Supervisor at the direction of the Executive Director.

The purposes for which money from this fund may be spent, and the priority of spending are:

- (1) Purchase and maintenance of technical equipment - such equipment would include electronic surveillance equipment, cameras, data processing equipment, etc.
- (2) Training (of Board employees) - such training would include seminars, workshops and schools, and technical investigative schools. Expenditures incurred would include seminar fees, air and/or ground travel, lodging and meals when necessary pursuant to Department of Administrative Services' guidelines.
- (3) Training (of other law enforcement officials and drug law enforcement officers) - such training would be offered only through a formal seminar or workshop developed by the Board staff and administered by Board employees.
- (4) Travel, and any expenses related to special or unusual investigations such as out-of-state travel, "buy money", etc.

This listing of purposes and priorities is not exclusive, and may be supplemented or revised by the Executive Director of the Board as requests for expenditures are made and all necessary approvals are obtained.

## **R-2009-058**

### **DRUG LAW ENFORCEMENT PROCEDURES [As adopted September 9, 2008]**

- (1) All felony violations will be reported to the appropriate prosecutor's office by submission of investigative reports.
- (2) All misdemeanor violations will be reported to the appropriate prosecutor's office - if the case also involves felony violations, by submission of investigative reports.
- (3) All misdemeanor violations that may warrant criminal prosecution, where felony violations are not found, will be reported to the Board office. These violations will be reported by the office staff to the Board president, or when appropriate the vice-president, to determine if the case will be reported to the appropriate prosecutor's office. All decisions regarding the filing of misdemeanor charges shall be made in writing and signed by the Board officer making such decision. The written documentation of the decision shall be maintained in the investigative file.
- (4) No employee of the Board will sign criminal complaints unless requested to do so by the prosecutor or the Board president or vice-president.

- (5) When no felony charges exist, no Board employee will sign misdemeanor complaints unless requested to do so by the appropriate officer of the Board or by a prosecutor's office.
- (6) In the event that the Board president or vice-president and the office staff are not in agreement on the filing of charges for misdemeanors, the matter will be presented to the full Board for its consideration. Investigative files may be reviewed by the president or vice-president with the Compliance Supervisor or Assistant Executive Director if deemed necessary.

**R-2009-059**

**ELECTRONIC VIDEO EQUIPMENT DISTRIBUTION AND USE  
[As adopted September 9, 2008]**

- (1) Electronic video equipment may only be utilized during the course of an authorized Board of Pharmacy investigation. When not being used for an authorized investigation, electronic video equipment shall be secured at the office of a designated agent.
- (2) An authorized investigation is any investigation assigned a case number by the Compliance Supervisor or Assistant Executive Director.
- (3) Prior to installation of equipment, the designated agent must obtain a signed "Permission for Installation" of Video Equipment form (Form PHA 0812). This form is to be maintained in the investigative case file and attached to a Report of Investigation.
- (4) Any use of electronic video equipment (regardless of whether a suspect was identified) must be documented in detail in a Report of Investigation submitted under the assigned case number.
- (5) The employee is responsible for the reasonable and prudent care of the equipment when it is in the employee's possession.

**R-2009-060**

**ERROR-IN-DISPENSING INVESTIGATIONS  
[As adopted September 9, 2008]**

- (1) Complaints of errors-in-dispensing shall be investigated by the field staff and documented in an Error-in-Dispensing Report (Form PHA-0808). The report format shall be designated by the Compliance Supervisor so that a database of pertinent information can be collected for use by the Board to identify potential hazardous public safety trends.
- (2) The written report will document the following information, if available:
  - (a) Whether the complaint was founded, unfounded, or could not be determined;
  - (b) The name(s) of those responsible for the error in dispensing;
  - (c) Circumstances that may have contributed to the error in dispensing such as:
    - Location of drug stocks;
    - Cluttered or disorganized pharmacy;
    - Misinterpretation of the prescription;
    - Poorly written prescription (such as failure to contact the prescriber for clarification);



- Lack of knowledge regarding drug products, (such as belief that drugs products were equivalent, unfamiliarity with drug, etc.)
- Dosage size, color, etc.;
- Impaired pharmacist;
- Failure to perform a drug utilization review;
- Failure to counsel;

(d) Action taken by the Board as a result of the investigation.

(e) Documentation of contact with the complainant to inform them of the findings and actions taken by the Board and some details of that conversation, or documentation as to why the complainant was not contacted.

**R-2009-061**

**FIELD STAFF HEADQUARTERS  
[As adopted September 9, 2008]**

**Introduction:**

The Ohio Board of Pharmacy has the statutory responsibility for enforcing, or causing to be enforced, Chapters 2925., 3715., 3719., and 4729. of the Ohio Revised Code. To carry out this legislative mandate in a cost-effective manner, the Ohio Board of Pharmacy has employees who reside throughout the state of Ohio and whose field office (headquarters) is located at the employee's place of residence. "Headquarters" as defined in paragraph (A)(2) of Ohio Administrative Code Rule 126-1-02 means, "the office address at which a state agent has their primary work assignment or if a state agent's primary work assignment involves regularly scheduled travel, the place from which they can most effectively carry out the assigned duties."

**Policies And Procedures:**

Because of the nature of the responsibilities of the field staff and the need for accountability for state-owned equipment possessed by the employee in the field for enforcement activities, and the need for such employees to be reached on an as-needed basis by the Board's office staff, law enforcement authorities, and persons engaged in the legal distribution of dangerous drugs in Ohio, the following policies shall apply and the procedures followed:

- (1) The location of any and all field offices shall be approved in writing. Field offices will not be approved until the sites and facilities that will be used as headquarters have been inspected by the Compliance Supervisor or an appropriate designee and a determination made that such an office (headquarters) is:
  - (a) Secure and not accessible by any unauthorized person without detection,
  - (b) Suitable for maintaining confidential documents and evidence obtained during an investigation,
  - (c) As much as is practical, centrally located within the assigned territory; and,
  - (d) Conducive to the drafting of required reports, the maintenance of proper records, and the use, storage, and maintenance of the equipment required to effectively carry out the employee's job responsibilities.
- (2) No employee in the field may change the location of their headquarters without obtaining written approval.
- (3) Territories shall be assigned to employees working in the field and shall be determined by:

- (a) The number and classification of sites that will be assigned to the employee,
- (b) The amount of travel time required to conduct a compliance inspection or investigation at an assigned site,
- (c) The area covered by the assigned territory; and,
- (d) The location of the employee's residence.

**R-2009-062**

**FIREARMS POLICY  
[As adopted September 9, 2008]**

Each Board agent shall sign and date an acknowledgement of this policy. Any violation of this policy will be grounds for discipline and may result in termination of employment.

**TRAINING**

Any Board agent who carries a handgun under this policy must meet the following requirements:

1. Completion of the Ohio Peace Officer's Basic Training Program (OPOTA) or an OPOTA equivalent program (out-of-state) and,
2. Annual successful re-qualification with each handgun and holster carried.

**DOCUMENTATION**

The following items must be on file with the Compliance Supervisor or Assistant Executive Director prior to carrying a handgun:

1. Documentation of completion of OPOTA or equivalent,
2. Documentation of successful annual re-qualification with each handgun carried,
3. Documentation of each handgun model and serial number carried. Only a handgun of the following calibers may be authorized:

.380 ACP	.357 magnum
9mm Luger	.40 S&W
38 Special	.45 ACP

**ANNUAL RE-QUALIFYING**

If re-qualifying through another agency, the Board agent must submit a current copy of the instructor's training certificate, along with the score sheet and course of fire to the Compliance Supervisor or Assistant Executive Director within two weeks of the date of re-qualification. Board firearms instructors shall submit a current copy of their instructor's training certificate to the Compliance Supervisor or Assistant Executive Director.

**METHOD OF CARRY**

The handgun shall be carried in an approved holster or secured in a manner that ensures the safety of the Board agent and the public. The method of carry shall be such that the possession of a handgun is not apparent or easily detectable to another.

The reckless, neglectful, blatant, or careless display of a handgun is a serious violation of this policy. Firearms shall not be carried into licensed sites when conducting routine duties.

## **USE OF FORCE**

The discharge of a handgun by a Board agent in the performance of the agent's duties, other than during training, is considered a use of force and must be reported to the Compliance Supervisor or Assistant Executive Director as soon as is reasonably possible.

Board agents may discharge a handgun in the performance of the agent's duties only under the following circumstances:

To defend themselves or another from an attack which the agent has reasonable cause to believe could imminently result in death or serious bodily harm to themselves or another in the immediate area;

In supervised training.

Board agents are prohibited from discharging a handgun in the performance of the agent's duties, under the following circumstances:

Merely to forestall the escape of a subject, whether a felony or a misdemeanor is alleged.

This policy specifically prohibits discharging a handgun at any fleeing suspect who poses no imminent threat to the agent or bystanders in the immediate area.

In any situation which involves no actual or threatened imminent attack, and which the agent has no reasonable cause to believe will imminently result in death or serious bodily harm;

As a warning or to attract attention;

At or from a moving vehicle, unless in extreme, exigent circumstances;

Toward or into a crowd or any gathering.

## **COST/EXPENSES**

The Board shall be responsible for expenses including wages and travel for annual re-qualification.

The Board shall reimburse agents via 4A5 funds for one-hundred rounds of duty ammunition for each qualifying weapon annually.

## **R-2009-063**

### **VACCINATION OF FIELD STAFF FOR HEPATITIS-B [As adopted September 9, 2008]**

Because certain employees of the Board of Pharmacy may be at risk of exposure on an intermittent basis to the Hepatitis-B virus during the performance of authorized duties, the Board of Pharmacy adopts the following policy:

- (1) All employees identified, through job-related functions, as having possible exposure to the Hepatitis virus will be offered, at no cost to the employee, the Hepatitis B vaccine;
- (2) Board staff will identify the proper process through state accounting to assure that the total cost incurred for the vaccine will be paid in a timely fashion;
- (3) The offer for the vaccine will be made immediately to all current employees identified above. This offer will be made to all new employees who meet the criteria of possible exposure. Further, this offer will be open to any employee identified as having

possible exposure to receive the vaccine at anytime in the future, at the employee's discretion.

**R-2009-064**

**INSPECTION REPORT  
[As adopted September 9, 2008]**

Dangerous Drug Distributor Inspection Reports will be made only on Form PHA-0610 and will be made on site during an inspection.

All inspection reports shall be completed as directed by the Board's supervisory staff.

All inspection reports shall be dated and signed by the employee.

All inspection reports shall reflect the actual date and time period of an inspection.

The Dangerous Drug Distributor Inspection Report (Form PHA-0610) shall be manually signed and dated by the on-duty pharmacist or Responsible Person before the Board's employee leaves the registrant's location.

**R-2009-065**

**ISSUANCE OF PINK SHEETS  
[As adopted September 9, 2008]**

A "Pink Sheet" Notice is a written reprimand issued by the Board to a licensed facility that requires a written response by the Responsible Person.

A "Pink Sheet" Notice is the first step in the disciplinary procedure, and is to be considered more serious than the recording of informational material placed on an inspection sheet during routine inspections.

After issuance of the second "Pink Sheet" Notice for the same or similar violation(s), the next step in the disciplinary process may be the issuance by the Board of Pharmacy of a "Cease and Desist" Order or a "Notice of Opportunity for Hearing". The seriousness of the violation(s) will determine which initial step(s) in the disciplinary process will be used.

A "Pink Sheet" Notice may be issued at the discretion of the Board agent, and may be for a wide variety of individual violations or deficiencies, or combinations thereof, during the conduct of business as a licensee or registrant.

A "Pink Sheet" Notice shall be issued for the following violations:

- (a) Keys or electronic access code to the pharmacy being in the possession of any person other than a registered pharmacist during non-business hours,
- (b) No controlled substance inventory (DEA biennial inventory) conducted and maintained within the last 24 months,
- (c) No controlled substance inventory taken when the Responsible Person changed,

Failure to have a Responsible Person employed at the site,

Failure to maintain or have access to state and federal laws, rules, and regulations regarding the legal distribution of drugs in Ohio,

Failure to offer patient counseling and documentation of refusal of counseling,

Failure to report theft or loss of a dangerous drug or controlled substance,

Failure to report required prescription data to Ohio Automated Prescription Reporting System (OARRS),

Error-in-dispensing investigations where it has been determined that an error actually occurred.

**R-2009-066**

**JURY DUTY  
[As adopted September 9, 2008]**

- (1) In order to be paid by the State of Ohio for jury duty, the following documentation must be submitted to the Board office:
  - (a) Verification from the Clerk of Courts that documents the days and hours on duty,
  - (b) The subpoena with a completed Request for Leave (Form ADM-4258) – the Form ADM-4258 shall be completed by the employee,
  - (c) Once an employee obtains a check in payment for jury duty, the employee is to photocopy that check prior to cashing it. The employee is to submit the photocopy along with a personal check (if needed) to reimburse the state for any funds in excess of the current provisions in the union contract. The personal check must be made payable to "Treasurer of the State of Ohio."
- (2) Failure to obtain the above information and documentation will result in loss of wages by the State of Ohio for the time spent on jury duty.

**R-2009-067**

**PROCESSING OF LATE APPLICATIONS FOR RENEWAL OF  
LICENSES TO PRACTICE PHARMACY  
[As adopted September 9, 2008]**

If a pharmacist submits an application for renewal of an identification card after September 15th, the following procedures will be followed by Board staff:

- (A) If this is the first time the renewal is late (license has lapsed for a period of less than 60 days):
  - (1) The application for renewal will be processed and the identification card will be issued if all requirements for renewal are met.
  - (2) If the Board staff has reason to believe that the pharmacist is currently practicing in Ohio without a license based on the records of the Board a written warning shall be issued pursuant to Ohio Revised Code (O.R.C.) Section 4729.25 to both the pharmacist (violating O.R.C. Sections 4729.12 & 4729.28), and terminal distributor of dangerous drugs (violating O.R.C. Sections 4729.27, 4729.28, & 4729.55 if responsible pharmacist; Section 4729.28 if employee pharmacist) employing the pharmacist. A copy of the written warnings shall be placed in the respective file folders for future reference.
- (B) If this is the first time the renewal is late (license has lapsed for a period of more than 60 days but less than three years):
  - (1) The application for renewal will be processed and the identification card will be issued if all requirements for renewal are met.

- (2) If the Board staff has reason to believe that the pharmacist is currently practicing without a license, follow paragraphs (C)(2) and (C)(3).
- (C) If this is the second time the renewal is late (license has lapsed for a period of less than three years):
  - (1) The application for renewal will be processed and the identification card will be issued if all requirements for renewal are met.
  - (2) If the Board staff has reason to believe that the pharmacist is currently practicing without a license, and a written warning has been issued pursuant to paragraph (A) above, a complaint form (Incident Report-Form PHA 0009) will be processed immediately. A Compliance Agent or Specialist will immediately conduct an investigation to determine whether the pharmacist has practiced during the lapsed time. If the pharmacist has practiced, a Notice Of Opportunity for a Hearing shall be issued as well as an offer to enter into a "Consent Agreement" (offer of disciplinary action such as suspension or monetary penalty based upon admission of guilt). A settlement agreement is a public record; the amount of the monetary penalty offered shall be based on the seriousness of violations such as the length of time practicing without current license. Maximum monetary penalty is \$500.00 for each day the pharmacist practices without a current license.
  - (3) If the pharmacist does not enter into a "Consent Agreement", the matter shall be adjudicated pursuant to current Board policies and procedures.
- (D) If the pharmacist is found in the actual practice of pharmacy by a Compliance Agent or Compliance Specialist when the pharmacist's identification card has been lapsed for a period of less than three years, then the following will apply:
  - (1) The pharmacist will be informed immediately that he or she may not legally practice pharmacy and a "Pink Sheet" will be issued to the terminal distributor of dangerous drugs employing the registered pharmacist who does not hold a current license. An affidavit may be filed with the court of jurisdiction charging the pharmacist with violating Ohio Revised Code Section 4729.28 following consultation with the Board staff and Board president or vice-president if circumstances warrant such an action.
  - (2) The application for renewal will be processed and the identification card will be issued if all requirements have been met. If this is the first time the renewal is late, and it is less than sixty days late, follow paragraph (A). If this is the first time the renewal is late and it is more than sixty days late, follow paragraph (B). If this is the second time the renewal is late, follow paragraph (C).
- (E) If the identification card has been lapsed for more than three years the identification card will not be issued until the pharmacist has met the requirements of Section 4729.13 of the Revised Code.

All actions by the Board for late renewal will be based on evidence that the pharmacist was in the actual practice of pharmacy during the lapsed time period, or that the pharmacist was in the actual practice of pharmacy during the lapsed time period based on Board record. If the investigation shows that the pharmacist has not practiced during the lapsed time, a report will be filed with the office. This late renewal will not be considered as a violation in the review of any future late renewal applications.

**R-2009-068**

**MONTHLY ACTIVITY REPORT  
[As adopted September 9, 2008]**

All field staff shall electronically submit to the Board office all daily activity reports for the previous month within five (5) working days following the end of each month.

**R-2009-069**

**WHEN THE NEXT YEAR'S LICENSE MAY BE ISSUED  
[As adopted September 9, 2008]**

Any terminal distributor purchasing and/or possessing dangerous drugs on or before October 31st of each year, will be issued the current year's license and a renewal application for the next licensure year. Any new terminal distributor who will be purchasing and/or possessing dangerous drugs for sale at retail for the first time after October 31st will be issued next year's license.

Any wholesale distributor purchasing and/or possessing dangerous drugs on or before April 30th of each year will be issued the current year's license and a renewal application for the next licensure year. Any new wholesale distributor who will be purchasing and/or possessing dangerous drugs for sale at wholesale for the first time after April 30th will be issued next year's license.

**R-2009-070**

**NOTARY PUBLIC  
[As adopted September 9, 2008]**

All field staff shall obtain and maintain a notary public commission. A newly hired employee must obtain a notary public commission in order to successfully complete the probationary period.

Field staff will notarize all written statements in which they have an active role.

The Board's supervisory staff may grant exceptions to this policy.

**R-2009-071**

**NOTICE OF OPPORTUNITY FOR A HEARING ISSUANCE APPROVAL PROCESS  
[As adopted September 9, 2008]**

Matters requiring investigation may be referred to the Board office staff in a variety of ways. The office staff will investigate and formulate a proposed Notice of Opportunity for a Hearing when warranted according to the facts and existing Board policy.

The Board office staff will take all appropriate steps to avoid any possible prejudices or biases and assure anonymity in the event the issuance of the Notice is denied. The proposed Notice will also be reviewed by the Assistant Attorney General for legal analysis. Questions, comments, or proposed changes can be interposed by either the Board President or the Assistant Attorney General. Should the Board President, Assistant Attorney General, or Executive Director have questions or concerns about the advisability of issuance, the proposed Notice may then be submitted to the entire Board for approval or denial.

**R-2009-072**

**PAYMENT OF COMPLIANCE SPECIALIST C.P.E.  
[As adopted September 9, 2008]**

The Board may pay the cost of continuing pharmacy education for the Compliance Specialists (maximum of \$500.00/employee) provided it is job-related and has been approved by the Compliance Supervisor or Assistant Executive Director.

**R-2009-073**

**REPORT SUBMISSION  
[As adopted September 9, 2008]**

**REPORTS OF INVESTIGATION:**

All reports of investigation submitted shall be legible and written in a complete, accurate, thorough, and professional manner. All reports are required to be submitted electronically to a supervisor for review and approval prior to submitting a hard-copy report to the Board office.

All employees will submit required reports in a timely manner upon the completion of an investigation, or after a significant event that requires a report to be submitted. An investigation shall be initiated within 45 days of receipt of the Incident Form.

Such reports will be submitted by the agent to whom the investigation was assigned unless the report is such that it must (or should be) submitted by another agent who is assisting the case agent. This would include review of OARRS data, patient profiles, medical records, etc. that are gathered as part of an investigation. The case agent is responsible for assigning all Report of Investigation (ROI) numbers.

No employee will depend on another agency to write reports for the Board's investigations. Such reports will reflect the activity conducted by Board of Pharmacy personnel. If another agency's reports are submitted as a part of the investigative file, a cover report will be submitted and the other agency's report shall be included as an attachment.

If an investigation is to be closed because there is no time to conduct the investigation based on other obligations and priorities, a report documenting the circumstances shall be filed within 45 days of receipt of the Incident Form (Form PHA-0009).

**CITATION – REQUEST FOR ISSUANCE:**

Reasons for requests for issuance of a citation (Notice of Opportunity for a Hearing) include summary suspensions, administrative hearings, cease and desist orders, and proposals to deny applications.

A request for issuance of a citation will be submitted to the Board's supervisory staff for review. They will determine proposed charges to be made by the Board against the registrant(s).

The Board's supervisory staff may request that the investigating employee obtain further evidence to support a particular charge. That request shall be completed in a timely manner.

The investigating employee will be given a draft copy of the proposed Board action requesting that the entire document be reviewed for accuracy and completeness. The investigating employee shall promptly compare the proposed citation with the investigative file and ensure that all of the information in the proposed Board action is supported by reports, investigative notes. Also, that the evidence such as the allegations correctly reflect evidence and facts, spelling of drug names, prescription numbers, etc. A final review will be made by the Compliance Supervisor prior to issuance.



**DIVERTED DRUG REPORT:**

A drug diversion is the transfer of a drug from the legitimate pharmaceutical drug distribution network into the illicit market.

A Diverted Drug Report (Form PBC-0809) is due for submission after the total amount of drug diversion has been determined. This report is to document the diversion of both dangerous drugs and controlled substances. Generic drug names are to be used unless brand-name drugs were actually diverted.

This report is to be submitted for all drug diversion discovered during an assigned investigation. This report will document only diverted drugs discovered as a direct result of the Board's active participation in an investigation. Only one diverted drug report will be submitted for each investigation.

**ARREST REPORT:**

An Arrest Report (Form PBC-0807) is due for submission at the time the arrest of the subject becomes known to the Board employee assigned to the investigation. This report is to be filled out only for an investigation in which the Board employee had a direct, active participation.

**DRUG FINE REPORT:**

A Drug Fine Report (Form PHA-0117) is due for submission at the time the arrest of the subject becomes known to the Board employee assigned to the investigation. This report is to be submitted with the Arrest Report.

**R-2009-074****REQUESTS FOR CASE NUMBER  
[As adopted September 9, 2008]**

All investigations will be conducted only by utilization of a case number.

No investigative report shall be submitted to the office without an assigned case number which shall be typed on the report.

Case numbers will be assigned by submission of an Incident Report (Form PHA-0009) electronically. After the request for a case number has been received by the office, it will be assigned a number and the investigation, at that time, will be assigned to a case agent/specialist. Lack of sufficient information will result in no case number being assigned.

**R-2009-075****REQUEST FOR LEAVE WITH PAY  
[As adopted September 9, 2008]**

This policy applies to vacation and personal leave.

Leave may be approved only after receipt by the Board's supervisory staff of a Request for Leave (Form ADM-4258). This form must be signed by the employee requesting leave with pay.

To facilitate this process, Board employees may provide pre-signed leave applications on file with, and available to, the Board's supervisory staff. Such forms may be approved and completed by a supervisor at the time a request for leave is made by an employee.

The employee shall submit written notification electronically to the fiscal, legal, and compliance sections of the Board office stating that the employee wishes to be placed on leave for a specific number of hours for a specific day.

Leave with pay will not be approved if it conflicts with any Board hearing or a subpoena for a court proceeding. The Board will make diligent efforts not to schedule hearings during previously scheduled leave.

**R-2009-076**

**SICK LEAVE  
[As adopted September 9, 2008]**

Sick leave may be approved only after receipt by the Board's supervisory staff of a Request for Leave (Form ADM-4258). Unless the employee is not physically capable of doing so, this form must be signed by the employee requesting sick leave.

To facilitate this process, Board employees may provide pre-signed leave applications on file with, and available to, the Board's supervisory staff. Such forms may be approved and completed by a supervisor at the time a request for leave is made by an employee.

The employee shall submit written notification electronically to the fiscal and compliance sections of the Board office stating that the employee wishes to be placed on sick leave for a specific number of hours for a specific day.

**R-2009-077**

**STATEMENT RECORD  
[As adopted September 9, 2008]**

The Statement Record (Form PHA-0800) is to be used when taking a statement from an individual during Ohio Board of Pharmacy business. A statement taken using this form will be made an attachment to a separate report and is not meant to be a stand-alone report. The Board's supervisory staff may grant exceptions to this policy.

**R-2009-078**

**USE OF THE BOARD OF PHARMACY'S NCIC NUMBER  
[As adopted September 9, 2008]**

- (1) On February 4, 1992, the Ohio Board of Pharmacy was granted a National Crime Information Center (NCIC) Number.
- (2) This number is restricted for use of criminal justice purposes only.
- (3) The reasons for obtaining this number were:
  - (a) In 1990, the Ohio Legislature granted the Board the authority to receive mandatory fines and asset seizures. To receive funds from the federal government, an agency must have an NCIC number.
  - (b) The NCIC number allows the Board's investigators to conduct a criminal background check on individuals under investigation by the Board when other law enforcement agencies are not actively involved in the investigation.
- (4) The Board of Pharmacy will not have a terminal in the Columbus office due to security reasons.
- (5) Any access to the NCIC system will be in the following manner:
  - (a) If a law enforcement agency is involved in an investigation, that agency will conduct any background investigation through NCIC by access through its terminal using the law enforcement agency's NCIC access number.

- (b) If an agency is not involved in an investigation, the Board's agents shall request an NCIC access through the Board office. This information will be provided directly to the Compliance Supervisor or Assistant Executive Director.
- (c) Before a request is made to the office, a case number must be assigned.
- (d) The office staff will contact the Ohio State Highway Patrol, Columbus office, to access NCIC under the Board's number. Any information obtained will be forwarded to the Board office from the Highway Patrol.
- (e) The office staff will then forward this information to the Board agent.
- (f) A record will be maintained in the office identifying the case number, request date, agent requesting information, staff person responsible for the request, and the individual run through the NCIC system.
- (g) Any access to the NCIC system, other than described above, is prohibited.

**R-2009-079**

**WRITTEN REQUEST TO INSPECT  
[As adopted September 9, 2008]**

Board issued credentials and business cards shall be carried at all times when working for the Board and being paid by the State of Ohio.

Business cards, as issued by the Board, shall be given to persons in any licensed location that a field staff employee enters for inspection.

**Rescinded Policies** - The revision of the field staff's policy and procedure manual also includes the following policy rescissions.

~	Distribution of Reports	R 89-147
~	Legibility of Reports	R 89-148
~	Final Reports of Investigation	R 89-150
~	Error-in-Dispensing Investigations	R 89-152
~	Monthly Activity Report	R 89-154
~	Pink Sheet Notice Issuance	R 89-159
~	Cease and Desist Order	R 89-160
~	Inspection of Multiple-Licensed Locations	R 89-165
~	Return of Licenses Being Held for Issuance of the Next Year's License	R 89-166
~	Pre-Printed/Stamped Prescriptions	R 89-167
~	Field Staff Visits to the Office	R 89-169
~	Prescribing or Dispensing of Selected Schedule II Stimulant Drugs	R 89-171
~	Arrest Reports	R 89-173
~	New Owner Responsibility for Previous Deficiencies or Problems	R 89-189
~	Procedure for Issuance of a Notice of Opportunity for a Hearing	R 90-006
~	Renewal Fee for Conducting Business with a Lapsed License	R 90-048
~	Drug Distribution Refunds	R 90-049
~	Refunding of Pharmacist Renewal Fees	R 90-050
~	Refilling Prescription of Practitioners who Lose Prescribing Rights	R 90-157
~	Inspection and Copies of Public Records Maintained by the Board	R 90-159
~	Licensing of, and Conducting of Compliance Inspections of First Aid Rooms	R 90-245
~	Use of Outdated Drugs in Teaching Labs	R 90-018
~	Procedure for Consideration of a Notice of Opportunity for a When a Chapter 119. Hearing is not requested	R 90-019
~	Drug Distributor Refunds	R 90-124

~	In Support of the Ohio Cancer Pain Initiative	R 91-131
~	Accepting Facsimile Copies	R 91-159
~	Position on Patient Counseling and Education	R 91-163
~	Bulk Amounts for Steroids	R 91-194
~	Return of Pharmacist Identification Card and Wall Certificate Upon Suspension or Revocation	R 91-242
~	Wholesale of Dangerous Drugs to Federal Facilities	R 91-245
~	Criteria for Settlement Agreements Regarding Late Renewals	R 91-254
~	Hearing Officer Criteria Established	R 91-255
~	Procedure Regarding Medical Malpractice Payment Reports	R 92-036
~	Refunds of Applicants Who Withdraw Applications Prior to Board Determining Not Qualified	R 92-067
~	Hospitals Destroying Practitioner's Private Practice Drugs	R 92-073
~	Rule 4729-5-17 Regarding Log Book Records Clarified	R 92-113
~	Drugs Approved for Collection of Drug Abuse Data	R 92-230
~	Summary Suspension Policy for O.R.C. Section 3719.121	R 92-276
~	Enforcement Oversight Policy	R 92-277
~	Granting of Continuances Policy	R 92-278
~	Debriefing	R 93-024
~	Destruction by Pharmacist and Non-Licensed Employee in an Institutional Facility Setting	R 93-031
~	Conditions Requiring Registration of Physical Therapy Practice Sites	R 93-148
~	Charging for Copies Made at Hearings	R 93-227
~	Multi-Dose Packaging	R 93-228
~	Ohio Pharmacy May Not Transfer Drugs to a Facility Unless it is Registered with the Ohio Board	R 94-052
~	Responsibility of the Pharmacy Servicing the Facility to Set Criteria and Identify Personnel who may Transmit Medication Orders	R 94-117
~	Sealing of Criminal Records	R 94-128
~	Orders for Drugs Needed Immediately for Long-Term Care Patients	R 94-129
~	Any Pharmacy with a Different Address Must Have a Separate Distributor License	R 94-146
~	Notification of Board Regarding Legal Actions	R 95-032
~	Policy Regarding Late Renewals Amended	R 95-171
~	Policy regarding Registrants Who Have Been Summarily Suspended and Have Not Requested a Hearing	R 95-172
~	Late Renewal of Dangerous Drug Distributor Licenses	R 95-195
~	Revision of Language Addressing Bulk Amounts When Drafting Notices of Opportunity Approved	R 95-220
~	Responsible Person for Terminal Distributor License for Site Where Non-Patient-Specific Drugs are Stored in Ohio	R 95-248
~	Procedure for Enforcement of Paragraph (B)(7) of Rule 4729-15-04	R 95-263
~	Medicinal Oxygen for Emergency Use by Laypersons (Non-Medical Personnel)	R 96-021

**R-2009-080**

Mrs. Gregg moved that the memorandum of understanding with the Attorney General's office concerning a continuation of the services of an Assistant Attorney General for FY 2009 be accepted by the Board and signed by Mr. Winsley. Mr. Kaderly seconded the motion and it was approved by the Board: *Aye* – 5.

2:15 p.m. Mr. Kaderly left the meeting for personal reasons.

2:33 p.m. The Board recessed for the day.

**Wednesday, September 10, 2008**

10:00 a.m. The Ohio State Board of Pharmacy convened at the Villa Milano Restaurant, 1630 Schrock Road, Columbus, Ohio, with the following members present:

Nathan S. Lipsyc, R.Ph., *President*; Elizabeth I. Gregg, R.Ph., *Vice-President*; Donald M. Casar, R.Ph.; Barton G. Kaderly, Public Member; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenhahn, R.Ph.

The Board was joined by the Board of Trustees of the Ohio Pharmacists Association (OPA) for a discussion of items of mutual interest.

Mrs. Droz presented a report on the Ohio Automated Prescription Reporting System (OARRS).

Mr. Keeley discussed the Legislative Report with the Boards.

Mr. McMillen discussed the Licensing Report with the Boards.

Other items of mutual interest were discussed. There were no items requiring official Board action.

11:40 a.m. The meeting with the OPA Board of Trustees ended.

**R-2009-081**

Mr. Winsley presented the tentative Board meeting schedule for FY 2010. Mr. Casar moved that the calendar be accepted and Mr. Wiesenhahn seconded the motion. It was approved by the Board: *Aye* – 5.

<b>2009</b>	<b>2010</b>
JULY 13, 14	JANUARY 4, 5, 6
AUGUST 3, 4, 5	FEBRUARY 8, 9, 10
SEPTEMBER 14, 15, 16	MARCH 8, 9, 10
OCTOBER 5, 6, 7	APRIL 5, 6, 7
NOVEMBER 2, 3, 4	MAY 3, 4, 5
DECEMBER 7, 8, 9	JUNE 7, 8, 9

11:42 a.m. Mrs. Gregg moved that the Board receive Per Diem as follows:

<u>PER DIEM</u>	<u>09/08</u>	<u>09/09</u>	<u>09/10</u>	<u>Total</u>
Braylock	1	-	-	1
Casar	1	1	1	3
Gregg	1	1	1	3
Kaderly	1	1	1	3
Kolezynski	1	-	-	1
Lange	1	1	1	3
Lipsyc	1	1	1	3
Pasquale	-	-	-	-
Wiesenhahn	1	1	1	3

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

11:43 a.m. Mrs. Gregg moved that the meeting be adjourned. The motion was seconded by Mr. Casar and approved by the Board: *Aye* – 5.

The Ohio State Board of Pharmacy  
approved these Minutes October 7, 2008