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Minutes of the July 13-14, 2009

Meeting of the Ohio State Board of Pharmacy

Monday, July 13, 2009

9:00 a.m. The Ohio State Board of Pharmacy convened at the Salt Fork Resort & Conference Center, Summit View Room, with the following members present:

Elizabeth I. Gregg, R.Ph., *President*; Heather L. Pasquale, R.Ph., *Vice-President*; Donald M. Casar, R.Ph.; Troy A. Gahm, R.Ph.; Barton G. Kaderly, Public Member; Richard F. Kolezynski, R.Ph.; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

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

R-2010-001 President Gregg administered the oath for a new Board member to Troy A. Gahm, R.Ph.

OATH OF NEW MEMBER

I, Troy A. Gahm, as a Member of the Ohio Board of Pharmacy do solemnly swear to uphold the Constitution of the United States and the State of Ohio; to impartially enforce the laws governing the profession of pharmacy and the legal distribution of drugs in the state of Ohio; and carry out the responsibilities of the Board as mandated by the laws of the state of Ohio without bias or prejudice, so help me God.

R-2010-002 Mr. Keeley presented the report on the reciprocity candidates meeting of July 9, 2009. The following candidates introduced themselves and then participated in a discussion of pharmacy laws and rules with Joann Predina.

Ken W. Akers	<i>Arizona</i>
Donna Haydee Alexander	<i>Massachusetts</i>
Robert Louis Armstrong	<i>Florida</i>
Courtney Marie Brown	<i>Louisiana</i>
Casey James Covrett	<i>North Carolina</i>
Neha Doshi	<i>Georgia</i>
Emily Kristine Dotson	<i>Illinois</i>
Lynn K. Fotis	<i>Iowa</i>
Elizabeth Gorevski	<i>New York</i>
Jason Alan Hackett	<i>Pennsylvania</i>
Thomas Edward Henry, III	<i>New York</i>
Angel Maria Hollrith	<i>North Carolina</i>
Scott Allen Hurm	<i>Indiana</i>

Joyce Kramer	<i>Kentucky</i>
Diann M. Kuder	<i>Pennsylvania</i>
Beth R. Mack	<i>Kentucky</i>
Esther Marie Molinaro	<i>Pennsylvania</i>
Khanh H. Trinh	<i>Pennsylvania</i>
Raelene Ellen Trudeau	<i>Texas</i>

President Gregg distributed the Board meeting seating arrangement and special Board member responsibilities for FY2010:

BOARD RESPONSIBILITIES AS SET FOR FY 2010

Wiesenhahn	<u>Continuing Education</u>
Gahm	<u>Administration/Probationary Reports</u>
Kolezynski	<u>Budget/Finance</u>
Lange	<u>Exams/Internship/Reciprocity</u>
Casar	<u>Legislation/Rules</u>
Pasquale	<u>Personnel</u>
Kaderly	<u>Licensure/Registration</u>
Joyce	<u>Consumer Affairs/Public Relations</u>
Gregg	<u>Compliance/Enforcement</u>

SPECIAL COMMITTEE APPOINTMENTS FOR FY 2010

Ad Hoc Advisory Committee on Rule Review ~ Casar; Pasquale

Nursing Board Committee on Prescriptive Governance ~ Casar

Medical Board P.A. Committee ~ Lange

R-2010-003

Mr. Kolezynski moved that Rule 4720-4-02 be approved for final filing, with the earliest possible effective date. The motion was seconded by Mr. Casar and approved by the Board: *Aye – 7.*

The Board meeting Calendar for FY 2011 was approved:

2010	2011
July 12-13	January 10-12
August 2-4	February 7-9
September 13-15	March 7-9
October 4-6	April 4-6
November 8-10	May 2-4
December 6-8	June 6-8

Mr. Keeley presented the following immunization training programs for approval, adding the Zoster vaccine training:

R-2010-004

Ms. Lange moved that the updated **University of Findlay** immunization program be approved. Mr. Gahm seconded the motion and it was approved by the Board: *Aye – 6/ Nay – 1.*

- R-2010-005** Ms. Pasquale moved that the updated **Kroger-Cincinnati (Dayton Division)**, immunization program be approved. Mr. Wiesenhahn seconded the motion. It was approved by the Board: *Aye – 6/ Nay – 1*.
- R-2010-006** Mr. Casar moved that the **Kroger-Columbus Division** supplemental Zoster vaccine program be approved. Mr. Kolezynski seconded the motion. It was approved by the Board: *Aye – 6/ Nay – 1*.
- R-2010-007** Mr. Gahm moved that the updated **Kroger-Columbus Division** program be approved. Ms. Lange seconded the motion and it was approved by the Board: *Aye – 6/ Nay – 1*.
- R-2010-008** After discussion, Mr. Gahm moved that the Board approve a resolution stating that those technicians who had passed one of the two examinations identified in Rule 4729-4-02 (A) prior to that examination receiving accreditation by the National Commission for Certifying Agencies be considered to have met the requirements for a Board approved examination. Mr. Casar seconded the motion and it was approved by the Board: *Aye – 7*.
- R-2010-009** The Board considered a request for an exemption to Ohio Administrative Code Rule 4729-5-11 (Responsible Person) requesting that **Vicki Lee DeAtley**, R.Ph. (03-2-23056) Cincinnati, Ohio be permitted to be the responsible person for the following sites:

Fitzgerald Pharmacy , Williamsburg, Ohio	(02-0102450)
Fitzgerald Pharmacy LTC , Williamsburg, Ohio	(02-1967600)

After discussion, Mr. Wiesenhahn moved that the Board approve the request for one year. The motion was seconded by Mr. Gahm and approved by the Board: *Aye – 7*.

Mr. Keeley discussed the Ad Hoc Committee on Rule Review's proposed changes including rules to be changed and the no-change rules, plus the miscellaneous rule changes. The proposed changes will be further discussed at the August Board meeting.

11:30 a.m. The Board recessed for lunch.

12:32 p.m. The Board reconvened with all members present.

Assistant Attorney General Tracy Marie Greuel and Mr. Rowland discussed the Ohio Sunshine Law and the state open-meetings regulations.

2:30 p.m. The Board recessed briefly.

2:39 p.m. The Board reconvened with all members present.

Assistant Attorney General Tracy Marie Greuel and Mr. Rowland discussed the "Notice of Opportunity for a Hearing" process and also reviewed the hearing process, and the process for case reviews.

Mr. Benedict and Mr. Reed discussed the process for Field Staff investigations, from the original complaint to the final report.

4.21 p.m. The Board recessed for the day.

Tuesday, July 14, 2009

8:31 a.m. The Ohio State Board of Pharmacy reconvened at Salt Fork Resort & Conference Center in the Summit View Room, with the following members present:

Elizabeth I. Gregg, R.Ph., *President*; Heather L. Pasquale, R.Ph., *Vice-President*; Donald M. Casar, R.Ph.; Troy A. Gahm, R.Ph.; Barton G. Kaderly, Public Member; Richard F. Kolezynski, R.Ph.; Deborah A. Lange, R.Ph.; and Jerome J. Wiesenbahn, R.Ph.

Also present were William T. Winsley, *Executive Director*; Timothy Benedict, *Assistant Executive Director*; Mark Keeley, *Legislative Affairs Administrator*; Chris Reed, *Compliance Supervisor*; Danna Droz, *Prescription Drug Monitoring Program Director*; and Tracy Marie Greuel, *Assistant Attorney General*.

R-2010-010

After discussion, Mr. Kolezynski moved that the Conference Call Board minutes of June 26, 2009, be approved as amended. Mr. Gahm seconded the motion and it was approved by the Board: *Aye* – 7.

R-2010-011

After discussion, Ms. Pasquale moved that the Board minutes of June 8-10, 2009, be approved as amended. Ms. Lange seconded the motion and it was approved by the Board: *Aye* – 7.

Mr. Casar said the Nursing Board Committee on Prescriptive Governance Report did not meet in June.

Ms. Lange said the Medical Board Physician Assistant Policy Committee did not meet in June.

Mr. Benedict said there was no report from the Medical Board Prescribing Committee this month.

Mr. Keeley presented the Legislative Report.

R-2010-012

After discussion, Mr. Casar moved that the Board grant Board staff the ability to grant waivers to Ohio Administrative Code Rule 4729-5-10 (Prescription pick-up station) without individual Board action to allow pharmacies to ship patient-specific chemotherapy prescriptions intended for direct administration by a healthcare professional directly to a prescriber's office setting 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.

9:28 a.m. The Board recessed briefly.

9:37 a.m. The Board reconvened with all members present.

Christopher Vaught presented to the Board a request from **Night Watch** for an after-hours remote medication-order review program for hospitals.

10:05 a.m. The meeting with **Night Watch** ended.

Mrs. Droz presented the Ohio Automated Prescription Reporting System (OARRS) report. She then presented the procedure changes as listed below for the Board members to review and approve.

Board Policies for implementation and operation of the Ohio Automated RX Reporting System (OARRS); July 2009.

Pharmacy Reporting Requirements:

1. Prescriptions that must be reported

Rule OAC 4729-37-02(A), (B) requires that:

- A pharmacy located in Ohio and licensed by the Ohio State Board of Pharmacy must report every outpatient prescription for any controlled substance, carisoprodol or tramadol.

- A pharmacy located outside Ohio and licensed by the Ohio State Board of Pharmacy must report every outpatient prescription for any controlled substance, carisoprodol or tramadol to an Ohio address.

Policy:

Outpatient RXs include, but are not limited to, those dispensed for:

- Patients living at “home” residences
- Patients in hospice
- Patients in assisted living facilities
- Prisoners in jails, but not prisons
- Hospital employees getting RXs from the hospital pharmacy
- Discharged hospital patients
- Hospital clinic patients
- ER patients by hospital/ED prescriber if > 24 hr supply
- Animals (veterinary RXs must be reported)

Exclusions include:

- Drugs dispensed for administration to Inpatients as defined by OAC 4729-17-01
 - ~ hospitals
 - ~ nursing homes & long term care facilities
 - ~ mental retardation & developmental facilities (MRDD)
 - ~ Rehabilitation facilities (prisons)
 - ~ psychiatric facilities
 - ~ convalescent homes
- Drugs “personally furnished” by a prescriber
- Drugs dispensed by a hospital’s ER prescriber if ≤ 24 hr supply
- C-Vs when purchased as OTC sale
- 1:1 drug replacements to EMS/Ambulance Services

1. Prescription information that must be reported

Rule OAC 4729-37-04(A) delineates the prescription information that must be submitted to OARRS.

Policy:

The Board will disseminate the prescription information requirements

- OSBP maintains a PMP Handbook that identifies the ASAP 2005 fields to be reported. The Handbook is available on the website or e-mailed upon request.
- Patient social security numbers may not be collected.
- Any data submitted by a pharmacy that is not required by OSBP, is removed when the file is processed. Therefore, the extraneous data is never entered into the OARRS database.

2. Wholesale sales that must be reported

Rule OAC 4729-37-04(B) requires that all wholesale sales, either by wholesalers or pharmacies, whether licensed as a WDDD or not, of any controlled substance, carisoprodol product or tramadol product to Ohio prescribers or Ohio TDDs where prescribers practice other than institutional facilities must be reported to OARRS. Information required for submission is delineated in OAC 4729-37-04(B).

Policy:

- Wholesale transactions are defined by ORC 4729.01(K).
- Drugs sold to prescribers “for office use” are wholesale sales, since they are not to be dispensed by prescription.

Rule OAC 4729-37-003:

The board of pharmacy shall identify the terminal distributors of dangerous drugs locations where prescribers practice and provide this information to all entities required to report sales at wholesale.

Policy:

Drugs sold to any purchaser not licensed as a pharmacy, hospital, or wholesale distributor of dangerous drugs is considered to be a drug location where prescribers practice.

3. How to Report**Rule OAC 4729-37-05:**

The Ohio Board of Pharmacy must identify the electronic format for pharmacies and wholesalers required to submit data to OARRS.

Pharmacy Policy:

- Access to the Ohio Automated RX Reporting System Handbook is provided to all TDDDs required to report data and available via the OARRS website. It will be reviewed and updated as needed.
- Board provides a method for direct entry of prescription information by pharmacy personnel via the OARRS web site. This is used in lieu of an Excel spreadsheet or paper reporting for any pharmacy that has internet access.
- If a pharmacy cannot submit data electronically, a waiver to allow paper reporting may be granted, upon written request.
- If a pharmacy experiences technical difficulties with reporting, a reasonable extension may be granted, upon written request.
- If the pharmacy **never** dispenses or sells a controlled substance, carisoprodol or tramadol, and the Board is notified in writing, a waiver from regular reporting may be granted.

Wholesaler Policy

- A wholesaler or pharmacy may submit sales transaction data via a csv file format provided by OARRS staff or by manual data entry on the website.
- Registration is required prior to first submission of data.
- If the wholesaler **never** dispenses or sells a controlled substance, carisoprodol or tramadol, and the Board is notified in writing, a waiver from regular reporting may be granted.

5. Acceptable Use of OARRS

ORC § 4729.79 sets forth the criteria for obtaining OARRS data:

Policy:

- OARRS clients are required to agree to an Acceptable Use Policy during the registration process and then have the responsibility to procure only the data that they are legally entitled to obtain according to this agreement.
- Acceptable Use Policy Types
 - ~ Prescriber (MD, DO, DMD, DDS, DPM, OD, NP (with CTP), PA with CTP)
 - ~ Prescriber's Delegate (NP, RN, LPN, PA)
 - ~ Pharmacist
 - ~ Law Enforcement Officer
 - ~ Probation Officer
- Acceptable Use Policies are available:
 - ~ On the WebCenter during on-line Registration process
 - ~ On the WebCenter under Related Links

~ On the WebCenter as links on the Log in page

Rule ORC 4729.79(A)(2) permits the Board to provide information to a federal officer, or a state or local officer of Ohio or any other state, whose duties include enforcing laws relating to drugs.

Policy:

Officers that are considered qualified law enforcement and may register as a user:

- Ohio Board of Pharmacy field staff
- Sworn officer of
 - ~ Police Department
 - ~ Sheriff's Office
 - ~ Drug Task Force
- Prosecutors and their investigators
- DEA agents & investigators
- Probation or parole officers (but only to monitor an offender's compliance with conditions of supervision)
- Other officers will be evaluated individually, upon request. Factors affecting approval or denial include but are not limited to
 - ~ Mission of the agency that employs the officer
 - ~ OPOTA (Ohio Peace Officer Training Academy) certification
 - ~ Statutory authority to investigate and/or prosecute drug offenses as defined in ORC 2925.01 (or equivalent federal or state law)

6. Release of Data that identifies a person

Rule OAC 4729-5-29 requires that the confidentiality of patient-identifiable health information available in the OARRS database will be maintained.

Policy:

- Reports that require manual processing of any OARRS request will be performed by an OSBP pharmacist.
- Client information or specific report issues will only be discussed by telephone after the caller's identity is verified as a current OARRS client.
- Patient information will not be disseminated over the phone.
- Notification of potential law violations to law enforcement or licensing boards based on data analysis will be done on letterhead or via e-mail, not by phone.

7. Release of De-Identified Data

Rule/Statute ORC4729.79(C) permits OARRS to release de-identified data for research or educational purposes. Database statistics and law enforcement outcomes will be provided in summary, statistical, or aggregate form.

Policy:

General Data

1. Data will cover entire state of Ohio or all non-Ohio data. Data for smaller geographical regions will not be released. Any exception must be approved by the PMP Administrator in consultation with the Executive Director and shall be structured to prevent the possible disclosure of protected health information.
2. Time frames for data will be no shorter than 3 months and shall be grouped in standard quarters, i.e. Jan-Mar, Apr-Jun, Jul-Sept, Oct-Dec.

3. Drugs will be identified by generic name only. Specific brands or specific formulations will not be identified.
4. Drugs may be grouped by ASHP category.
5. There is no charge for data, if provided electronically. Non-electronic data charges may cover only the cost of materials.

Once de-identified data is analyzed and shared with anyone other than OARRS staff, the information is considered public record.

Public records consist of:

- Statewide data
 - ~ Data will not be analyzed by zip code, county or region
- A minimum of 3 months timeframe
- Generic drug names
 - ~ No brand names or single product entities will be identified

Routine public record releases will be disseminated to:

- The Ohio State Board of Pharmacy during monthly meetings
- Grant Repots semi-annually or as required by the grantor
- OSBP staff for OARRS client marketing/educational sessions and law or CE presentations
- Legislative committees biennially, as required by law

Research Data:

Researcher must submit protocol and IRB approval before de-identified data is released.

Protocols must include:

- The reason for the study and anticipated outcome (i.e., publication, presentation at scientific meeting, etc.)
- Data fields and time frame requested
- Agreement that use of the data is limited to the protocol terms.
 - ~ If data is to be re-used, another protocol and IRB approval is required.
- Agreement that the data cannot be transferred/shared with anyone outside the specific research project for which it is approved
- Agreement that research results will be reported to the PMP Administrator and that OSBP may use the results for OARRS related purposes (e.g. reports to legislature)

OARRS staff will track all approved protocols and retain a copy of all data released pursuant to protocol.

8. Security

Policy: OARRS servers are backed up on a regular, routine basis to protect the integrity of the databases.

- Servers are backed up daily.
 - Backup disks and tapes are secured off-site.
 - OARRS data is not stored on a desktop or a laptop.
 - Desktop and laptop computers will be backed up on an ad hoc basis because all OARRS data and documents are stored on the servers.
 - Physical and electronic access to the servers is limited to the PMP Administrator and the IT staff.
 - All computers and servers comply with Ohio IT security policies.
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R-2010-013

After discussion, Mr. Gahm moved that the procedures be approved. The motion was seconded by Ms. Lange and approved by the Board: *Aye* – 7.

R-2010-014

Mr. Wiesenhahn moved that the **Night Watch** request for an after-hours remote medication-order review program for hospitals be found approvable pending final inspection. The motion was seconded by Ms Lange and approved by the Board: *Aye* – 6; *Nay* - 1 The Board requested a report after the following the inspection.

11:35 a.m.

Ms. Pasquale moved that the Board receive Per Diem as follows:

PER DIEM	07/13	07/14	Total
Casar	1	1	2
Gahm	1	1	2
Gregg	1	1	2
Kaderly	1	1	2
Kolezynski	1	1	2
Lange	1	1	2
Pasquale	1	1	2
Wiesenhahn	1	1	2

Mr. Kolezynski seconded the motion and it was approved by the Board: *Aye* – 7.

11:35 a.m.

Mr. Gahm moved that the meeting be adjourned. The motion was seconded by Mr. Casar and approved by the Board: *Aye* – 7.

The Ohio State Board of Pharmacy approved these Minutes August 3, 2009
