

OPEN MINUTES
Missouri Board of Pharmacy
December 13-15, 2006
Courtyard by Marriott
3301 LeMone Industrial Boulevard
Columbia, MO 65203

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. To better track the order in which items were taken up on the agenda, each item in the minutes will be listed in the order it was discussed at the meeting. The regular meeting was called to order by President Doug Lang at 8:30 a.m. on December 13, 2006.

Board Members Present

Doug Lang, R. Ph., President
Pamela Marshall, R. Ph., Vice President
Melissa Graham, R.Ph., Member
Gary Sobocinski, R.Ph., Member
Anita Parran, Public Member

Board Members Absent

Elaina Wolzak, R. Ph., Member

NOTE: One board member position vacant due to resignation of Tim Koch.

Staff Present

Tom Glenski, R. Ph., Chief Inspector
Tammy Siebert, Executive Assistant
Frank VanFleet, Inspector

Others Present

Curtis Thompson, Atty.
Kathleen Fitzgerald, Attorney General's Office
Susan McCann, BNDD

President Lang requested a moment of silence in memory of Board of Pharmacy Inspector John W. Heavin who passed away November 26, 2006.

MOTION TO CLOSE 8:33 AM

Anita Parran made a motion that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021 (1), (3), (5), (7), (13) and (14), RSMo, and under Section 620.010.14 (7), RSMo. Seconded by Gary Sobocinski to go into closed session at 8:33 a.m. Motion passed 4:0:0:1 with roll call vote as follows:

**Gary Sobocinski – yes
Pam Marshall – yes**

**Melissa Graham – yes
Elaina Wolzak – absent**

Anita Parran – yes

RETURN TO OPEN 12:30 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board went into open session.

#A2 Agenda Additions/Corrections

Tom Glenski reported on various additions and corrections to open session agenda items, including the continuance of Item #B2 to the February meeting.

#B2 Jeffrey Barnes, #40958, #2004-006460-F1- The following were included in the agenda materials:

- Notice Of Felony Disciplinary Hearing
- Complaint
- Entry of Appearance of counsel and Motion for Continuance received 12/8/06
- Notice of Continuance dated 12/8/06

#B1 Charles William Marsh #028481, #2005-006278-V1 – The Board reviewed the following:

- Notice Of Hearing On Violation Of Disciplinary Order
- Complaint

A violation of discipline hearing was scheduled for December 13, 2006, 1:30 p.m., 1st case on the docket. A court reporter was present and the hearing began at 1:26 p.m. The hearing concluded at 2:20 p.m. and a copy of the transcript is on file with the Board of Pharmacy.

MOTION TO CLOSE 2:21 PM

Gary Sobocinski made a motion that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), and (14), RSMo, and under Section 620.010.14(7), RSMo. Seconded by Melissa Graham to go into closed session at 2:21 p.m. Motion passed 5:0:0:0 with roll call vote as follows:

**Gary Sobocinski – yes
Pam Marshall – yes**

**Melissa Graham – yes
Elaina Wolzak – yes**

Anita Parran – yes

THURSDAY, DECEMBER 14, 2006 10:05 PM

By motion duly made, seconded, passed and recorded in closed session minutes, the Board went into open session.

FRIDAY, DECEMBER 15, 2006 8:33 AM
RECONVENE

The meeting reconvened in open session at 8:33 a.m. on Friday, December 15, 2006. All parties were present as previously recorded, except Curt Thompson, plus visitors as indicated in the visitor register.

#D2 Missouri Medicaid Presentation – The Board reviewed the following:

- Copies of slides provided by George Oestreich.

George Oestreich, Deputy Division Director of Clinical Services, Missouri Division of Medical Services, provided a Powerpoint presentation titled Missouri Medicaid Building on Health Information Technology Successes to Transform the System. Mr. Oestreich responded to questions by Board members and the public, and concluded his presentation at 9:28 a.m. President Lang stated that the Board would include an article in its quarterly newsletter concerning the new Medicaid technology.

CURT THOMPSON JOINED THE MEETING AT 9:05 A.M.

#A1 Approval of Minutes:

1. September 30, 2005 Conference Call Meeting
2. February 2006 Board Meeting
3. February 24, 2006 Conference Call Meeting
4. April 2006 Board Meeting
5. July 2006 Board Meeting
6. November 20, 2006 Conference Call Meeting

September 30, 2005 Conference Call - Discussion was held. **Motion was made by Melissa Graham and seconded by Anita Parran to approve the minutes of the September 30, 2005 open session conference call meeting as printed. Motion passed 5:0:0:0.**

February 8-10, 2006 Board Meeting – Discussion was held. **Motion was made by Gary Sobocinski and seconded by Melissa Graham to approve the minutes of the February 8-10, 2006 open session meeting as printed. Motion passed 5:0:0:0.**

February 24, 2006 Conference Call Meeting – Discussion was held. **Motion was made by Elaina Wolzak and seconded by Melissa Graham to approve the minutes of the February 24, 2006 open session conference call meeting as printed. Motion passed 5:0:0:0.**

April 19-21, 2006 Board Meeting – Discussion was held. **Motion was made by Melissa Graham and seconded by Elaina Wolzak to approve the minutes of the April 19-21, 2006 open session meeting as printed. Motion passed 5:0:0:0.**

July 12-14, 2006 Board Meeting – Discussion was held. **Motion was made by Gary Sobocinski and seconded by Pam Marshall to approve the minutes of the July 12-14, 2006 open session meeting as printed. Motion passed 5:0:0:0.**

November 20, 2006 Meeting - Discussion was held. **Motion was made by Gary Sobocinski and seconded by Anita Parran to approve the minutes of the November 20, 2006 open session meeting as printed, with a notation of the time Elaina Wolzak joined the meeting. Motion passed 5:0:0:0.**

#A3 Board Member Report

Pam Marshall reported that she and Doug Lang attended the annual District VI meeting October 26-28 in Little Rock, Arkansas. Doug Lang reported concerning the program content, and indicated that Louisiana's Malcolm Broussard was elected as the new District VI secretary/treasurer, replacing Kevin Kinkade.

Pam Marshall reported that she attend a Future Trek System meeting sponsored by Express Scripts, and that a Walgreens' 6th-year pharmacy student attended with her. Ms. Marshall made a presentation to several 6th grade students during this meeting.

Pam Marshall reported that she and Dennis Hunt attended an Illinois Professional Health Program regarding impaired professionals.

Doug Lang reported that he and Anita Parran attended the NABP Fall Educational Conference in Savannah, Georgia, November 3-4, 2006.

President Lang reported concerning Board Inspector John Heavin's death and a moment of silence was observed in his honor.

#A4 Board Member Update to phone, address, e-mail, fax # - No changes were reported by Board members.

#A5 General Administration Report:

- Policy on applicants eligible to test for NAPLEX/MPJE - Tom Glenski reported regarding change in Board office policy regarding allowing examination applicants to test for NAPLEX and MPJE in situations when possible discipline and/or pending legal matters are being reviewed by the Board. Discussion was held.
- Board of Pharmacy Consumer Report, 2004 Information for Consumers – Tammy Siebert reported that the Consumer Report was initiated at the request for a former Board member and that most of the information contained in the report is also provided in the Board's Annual Report, which is published on the Board's website. Doug Lang reported that this is duplicating work for office staff. **Motion was made by Gary Sobocinski and seconded by Pam Marshall to discontinue publication of the Consumer Report. Public Member Anita Parran concurred with the decision. Motion passed 5:0:0:0.**
- CE Audit – Tammy Siebert and Doug Lang reported that pharmacist renewals ended 10/31/06, and the CE audit will be initiated in January. Gary Sobocinski and

Pam Marshall provided additional comments concerning prior audit problems observed, that it is the pharmacists responsibility to maintain proof of their CE credits, dates for the period audited, etc. Discussion was held.

- Legislation Updated – Tammy Siebert reported regarding approval by the Department and Governor's Offices to pursue legislation as previously proposed. Doug Lang suggested use of the Division Professional Registration Committee person as sponsor for the legislation due to the executive director vacancy at this time. Ron Fitzwater reported that this year's Missouri Pharmacy Association legislation is essentially the same as last year's HB1168, and Representative Jay Wasson and/or Representative Steve Tilley will be sponsors of the legislation this year.
- Board Retreat – Tammy Siebert reported that The Keeter Center at School of the Ozarks, Point Lookout, Missouri, had been awarded the contract for the March 7-9, 2007 Board Retreat meeting.

#DH6 Mallinckrodt Inc., 675 McDonnell Boulevard, Hazelwood, Missouri 63042 – The Board reviewed the following:

- Intern Training Pharmacy Application – Special Site (Renewal)

Discussion was held regarding allowing the pharmacy schools to handle special site applications, so that the Board will review them as they do the school's intern training sites and preceptors annually. **Motion was made by Gary Sobocinski and seconded by Elaina Wolzak to approve this special site application for 500 hours. Motion passed 5:0:0:0.**

#DH7 Partner Therapy Meeting – The Board reviewed the following:

- Inspector Mike Kidd's memorandum dated 10/24/06
- Inspector Mike Kidd's memorandum dated 11/20/06

Doug Lang gave a verbal report on this matter.

RECESS FOR BREAK 10:10 – 10:22 A.M.

#C5 20 CSR 2220-2.450 – Fingerprint Requirements – The Board reviewed the following:

- Proposed Amendment published in Missouri Register 10/2/06.

No comments were received. **Motion was made by Gary Sobocinski and seconded by Elaina Wolzak to approve the proposed amendment to 20 CSR 2220-2.450 Fingerprint Requirements for Final Order of Rulemaking. Motion passed 5:0:0:0.**

#C7 20 CSR 2220-5.020 – Drug Distributor Licensing Requirements – The Board reviewed the following:

- Proposed amendment published in Missouri Register 10/2/06

No comments were received. **Motion was made by Elaina Wolzak and seconded by Pam Marshall to approve the proposed amendment to 20 CSR 2220-5.020 Drug Distributor Licensing Requirements for Final Order of Rulemaking. Motion passed 5:0:0:0.**

#C8 20 CSR 2220-5.030 – Definitions and Standards for Drug Wholesale and Pharmacy Distributors – The Board reviewed the following:

- Proposed amendment published in Missouri Register 10/2/06
- Comments from Matthew Van Hook on behalf of PhRMA received 11/1/06
- Comments from Bart Barefoot, GlaxoSmithKline received 11/3/06

Matthew Van Hook of Engel & Novitt, LLP, on behalf of Pharmaceutical Research and Manufacturers of America (PhRMA) stating PhRMA believes the time frame for reporting is too short and suggested changing (3)(M)6. from three (3) business days to ten (10) days. **Motion was made by Anita Parran and seconded by Gary Sobocinski to change 6. and 7. from three (3) to seven (7) business days, keeping the reporting period the same for consistency purposes. Motion passed 5:0:0:0.**

Bartley Barefoot, GlaxoSmithKline submitted a comment concerning reporting known or suspected instances of drug counterfeiting, theft or diversion to the board. State-by-state reporting requirements imposed on pharmaceutical manufacturers operating on a nationwide basis are an inefficient approach and are not necessary in light of enforcement efforts already taking place at the federal level. Mr. Barefoot requested drug manufacturers be exempted from the proposed reporting requirements in (3)(M)4.-7. It was the Board's consensus to make no change to the proposed regulation as commented by Mr. Barefoot.

Motion was made by Gary Sobocinski and seconded by Melissa Graham to approve the proposed amendment to 20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors for Final Order of Rulemaking, with revisions as previously noted. Motion passed 5:0:0:0.

#C6 20 CSR 2220-2.900 – Automated Dispensing and Storage Systems – The Board reviewed the following:

- Proposed amendment published in Missouri Register 10/2/06.
- Comments from MPA received 11/2/06

Ron Fitzwater, Missouri Pharmacy Association, submitted a comment indicating the amendment would minimize the patient-pharmacist relationship and would lose an effective patient counseling opportunity. Verbal comments were provided at the meeting by Ron Fitzwater; David Overfelt of NACDS; Susan Bricker of BJC Healthcare, Inc., St. Louis; and Bert McClary of BNDD. It was also suggested that in (1)(J) the word "federal" be replaced with "Food and Drug Administration". Doug Lang commented that the last portion of the last sentence in (1) be deleted, Gary Sobocinski commented regarding (3)E. to add at the end of the last sentence "within the line of sight of the pharmacy personnel."

Motion was made by Pam Marshall to accept revision suggested by Bert McClary and reject other comments. Motion died for lack of a second.

Motion was made by Melissa Graham and seconded by Anita Parran approve the proposed amendment to 20 CSR 2220-2.900 Automated Dispensing and Storage Systems for Final Order of Rulemaking, with revisions as previously noted to omit the last part of (1) as suggested by Doug Lang and as commented by Bert McClary regarding (1)(J). Motion passed 4:1:0:0, Pam Marshall opposed.

#C4 20 CSR 2220-2.190 – Patient Counseling – The Board reviewed the following:

- Proposed Amendment published in Missouri Register 10/2/06
- Comments from MPA received 11/2/06

Ron Fitzwater, Missouri Pharmacy Association, submitted a comment stating a direct patient-pharmacist relationship is vital for optimum therapeutic outcomes from a medication regimen. MPA believes the offer to counsel may be lost if provided by automated dispensing machines to patients. Discussion was held. It was Board consensus that the change previously made to 20 CSR 2220-2.900 alleviates this concern and made no change to the proposed regulation. **Motion was made by Gary Sobocinski and seconded by Anita Parran to approve the proposed amendment to 20 CSR 2220-2.190 Patient Counseling for Final Order of Rulemaking. Motion passed 5:0:0:0.**

#C2 20 CSR 2220-2.020 – Pharmacy Permits – The Board reviewed the following:

- Proposed Amendment published in Missouri Register 10/2/06
- Email with attachments from Carey Potter/Kevin Nicholson, NACDS, received 10/27/06
- Comments from MPA received 11/2/06

Kevin Nicholson, National Association of Chain Drug Stores, submitted a written comment regarding (9)(D) and (K), and David Overfelt of NACDS provided verbal comments concerning Mr. Nicholson's letter. The concern was that pharmacies that compound smaller number of products in batch quantity must obtain a separate license. The Board clarified it was not their intent to require new licenses in these situations, but that a revision to existing licenses to include specific pharmacy classifications is what is being required. It was the Board's decision to delete "... and meets **[one (1) of]** the following criteria:" **"[1. A product which will act systemically, regardless of the route of administration, and is prepared from bulk ingredients; or]";** renumber 2. to 1.; and change the new 1. to read "Any product made from any bulk active ingredient in a batch quantity as defined in 20 CSR 2220-2.400(3)."

Kevin Nicholson's comment requested clarification that "Class K: Internet" would apply only to pharmacies that are not otherwise licensed by the Board. MPA's comments concurred with Mr. Nicholson's comment. The Board reiterated that Class K: Internet is a permit classification, and would not require a new license, but would require a revision to existing licenses to include those specific classifications. The Board amended (K) as follows: "... medicines or poisons for any new prescriptions originating from the Internet for greater than ninety percent (90%) of the total new prescription volume on any day."

Motion was made by Pam Marshall and seconded by Anita Parran to approve the proposed amendment to 20 CSR 2220-2.020 Pharmacy Permits for Final Order of Rulemaking, with revisions as previously noted. All in favor, none opposed.

RECESS FOR BREAK 11:45 -11:55 AM

#C3 20 CSR 2220-2.025 – Nonresident Pharmacies – The Board reviewed the following:

- Proposed amendment published in Missouri Register 10/2/06
- Email with attachments from Carey Potter/Kevin Nicholson, NACDS, received 10/27/06
- Comments from Fred S. Brinkley, Medco Health Solutions, Inc. received 5/3/06

David Overfelt, NACDS, verbally commented on Kevin Nicholson's written comments. Dennis Hunt of Walgreens Corporation provided verbal comments. Discussion was held. It was determined the amendment as proposed could cause all pharmacists in nonresident pharmacies to need licensure in Missouri if they are accessing computer information in Missouri from their nonresident location. It was also noted that the fiscal note with this amendment would be inaccurate because of the number of nonresident pharmacists that would be required to be licensed in Missouri. **Motion was made by Gary Sobocinski and seconded by Pam Marshall to withdraw the proposed amendment to 20 CSR 2220-2.025 Nonresident Pharmacies from further processing. Motion passed 5:0:0:0.**

#C1 20 CSR 2220-2.010 – Pharmacy Standards of Operation – The Board reviewed the following:

- Proposed amendment published in Missouri Register 10/2/06
- Comments from Chief Inspector Tom Glenski received 11/30/06

Chief Inspector Tom Glenski reported that the rule amendment was based primarily on a mail order pharmacy's proposed remote verification system allowing a pharmacist to verify prescription information from their home. Mr. Glenski requested the Board consider two additional scenerios: 1) remote verification services for hospitals; and 2) a pharmacist providing drug utilization review and disease state management for retail pharmacies. Mr. Glenski suggested:

1. Amend paragraph (9)(A) to include language that prohibits patients from being seen at a Class I pharmacy in a residence. Add "5. Patients are not allowed in the pharmacy." Gary Sobocinski suggested revising (A)1. to read "The pharmacy must be located in a separate room that provides for a door with suitable lock;"
2. Amend paragraph (9)(B)1. to state "... All pharmacists working at the pharmacy shall be required to sign the manual ..." to address a situation where a pharmacist is under contract with a pharmacy instead of being an employee.
3. Amend paragraph (9)(B)2. to require the permit holder to be responsible for training since the pharmacist-in-charge is likely to be the only pharmacist working at the location. It was the Board's determination to delete "pharmacist in charge or the" from 2.
4. Amend paragraph (9)(B)3. to ensure overall compliance with the audit. Mr. Glenski proposed the following changes to 3. "The permit holder must complete an audit to ensure compliance with pharmacy policy and procedures and this

regulation at a minimum of twice per year, through physical visits by representatives of the permit holder. Audit results must be maintained by the permit holder for a period of three (3) years.”

5. Amend (9)(B) by adding 4. to include “If the pharmacist is working under a contract for the permit holder, a copy of the contract shall be available during an inspection.”
6. Delete subsections (9)(C) and (D) to be more generic allowing for differences in technology, and put the responsibility on the permit holder to ensure adequate security. Mr. Glenski proposed to delete (D) and add a new (9)(C) as follows:
“(C) Security-Records and Internet –
 1. All electronic data processing systems must meet all applicable state and federal confidentiality laws and regulations;
 2. Data processing systems must utilize sufficient security software; and
 3. Any breach in the security of the system must be documented and reported to the board of pharmacy within seven (7) days of the breach of confidentiality. Such documentation shall be available during an inspection.”
7. Define the term “permit holder” used throughout subsection (9)(E); Add at the end of the existing 1. “The permit holder for this permit must be the pharmacy the individual pharmacist is employed by or contracted with;” Change the second sentence of 2. to “Notification by the inspector to the permit holder will be provided a minimum....” And change the last sentence of 2. to “The permit holder must arrange for a designated representative to be present that is not a resident...”. Change 4. to read “The audits required in paragraph (9)(B)3. shall be available for review during the inspection; and”

Bert McClary of BNDD commented that the word “are” should be deleted from (9). Dennis Hunt, Walgreens Corporation, commented regarding (E).

Motion was made by Gary Sobocinski and seconded by Melissa Graham to approve the proposed amendment to 20 CSR 2220-2.010 Pharmacy Standards of Operation for Final Order of Rulemaking, with revisions as noted herein. Motion passed 5:0:0:0.

#D1 Pharmacy Services from Outside the Hospital – The Board reviewed the following:

- Memo from Susan McCann and Bert McClary of BNDD dated 11/14/06

Discussion was held. **Motion was made by Gary Sobocinski and seconded by Elaina Wolzak to conduct an open forum at a future meeting for further discussion of this matter. Motion passed 5:0:0:0.**

THE BOARD REVIEWED THE FOLLOWING ITEM FROM SECTION E THAT DID NOT REQUIRE INDIVIDUAL DISCUSSION OR ACTION.

#E1 Motion Language for New Rules/Amendments

NOTE: DUE TO TIME CONSTRAINTS, ITEMS #D3-D5 WERE TABLED FOR DISCUSSION AT THE FEBRUARY MEETING

MOTION TO ADJOURN OPEN MEETING 1:51 PM

At approximately 1:51 p.m., motion was made by Pam Marshall and seconded by Melissa Graham to adjourn the December 13-15, 2006 meeting. Motion passed 5:0:0:0.

DEBRA C. RINGGENBERG, R.PH.
EXECUTIVE DIRECTOR

DATE APPROVED: 9/14/07