

OPEN MINUTES
Missouri Board of Pharmacy
December 17-19, 2003
Holiday Inn Select
Columbia, MO

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 Elaina Wolzak at 1:00 p.m. on December 17, 2003.

Board Members Present

Elaina Wolzak, R.Ph., President
Doug Lang, R.Ph., Vice-President
Barbara Dunning, R.Ph., Member
Timothy Koch, R.Ph., Member
Marty Michel, R.Ph., Member
Gary Sobocinski, R.Ph., Member
Anita Parran, Public Member

Staff Present

Kevin Kinkade, R. Ph., Executive Director
Tom Glenski, R. Ph., Chief Inspector
Mike Kidd, R. Ph., Inspector
Kim Kaufman, R. Ph., Inspector

Others Present

Ron Smith, Assistant Attorney General
Daryl Hylton, Assistant Attorney General

Motion to Close 1:03 p.m.

Marty Michel 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 610.021.14 (1), (3), (5), (7), (13) and (14) and under Section 620.010.14 (7). Seconded by Doug Lang. Motion passed 6:0:0:0 with roll call vote as follows:

Barbara Dunning – yes
Marty Michel – yes

Doug Lang – yes
Tim Koch – yes

Anita Parran – yes
Gary Sobocinski – yes

Return to Open 10:13 p.m.

Upon motion duly made, seconded, passed and recorded in closed session minutes, the Board went into open session at approximately 10:13 p.m. on December 17, 2003.

Legislation – Discussion was held concerning policy issues and strategies regarding the Missouri Pharmacy Association’s proposed legislation. Kevin Kinkade reported on other states’ statistics concerning subpoena authority, recoupment of costs, expedited hearing authority, and embargo powers.

Motion to Close 10:45 p.m.

Doug Lang 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 610.021.14 (1), (3), (5), (7), (13) and (14) and under Section 620.010.14 (7). Seconded by Tim Koch. Motion passed 6:0:0:0 with roll call vote as follows:

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

THURSDAY, DECEMBER 18, 2003

Return to Open 3:31 p.m.

Upon motion duly made, seconded, passed and recorded in closed session minutes, the Board went into open session at approximately 3:31 p.m. on December 18, 2003.

#1 **Approval of Minutes**

The Board reviewed printed minutes of the August 21, 2003, Conference Call Meeting. **Motion was made by Doug Lang and seconded by Marty Michel to approve the minutes of the August 21, 2003 Conference Call Meeting as printed. Motion passed 6:0:0:0 with roll call vote as follows:**

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

#2 **Agenda Additions/Corrections**

Kevin Kinkade reported on various additions and corrections to the printed agenda.

#3 **Board Member Report**

Marty Michel reported on his attendance at a Professional Compounding Centers of America (PCCA) meeting.

Barbara Dunning reported on her attendance at the American Society of Consultant Pharmacists meeting.

Doug Lang reported on his University of Missouri-Kansas City ACPE site visit on September 16-18, 2003; his attendance at the NABP District VI Meeting in New Orleans, Louisiana, November 6-8, 2003; and his attendance at the ASHP National Meeting.

Kevin Kinkade congratulated the Board for their great efforts put into the Senate Hearing.

#4 Board Member Update to phone, address, e-mail, fax #

Elaina Wolzak provided new address and telephone information.

#5 General Administration Report:

a) General Operations – Kevin Kinkade reported that Scott Hamilton and Laura Payton had been hired in November to fill the vacant Licensing Technician I positions. Staff is drowning in a sea of work, they simply cannot keep up, there is a real workload issue. The appeal letter to replace Sharon Roberts' position has received no response from the Office of Administration. The office is in major need of reorganization--Tammy Siebert is currently covering two desks. Staff will be reviewing all positions for ways to become more efficient, such as possible changes to the intern training program. Thus far, the telephone voice mail system has been updated; application forms can be requested via a voice mail box; the web site is being revised; additional forms will be downloadable from the web site; monitoring of the Quality Assurance Program has been transferred to Inspector Kidd; a Division Central Investigation Unit person is processing investigation requests; prior history information will no longer appear in the agenda materials; and office staff will no longer draft felony and violation complaints--they are being referred to legal counsel for drafting; and Nancy Gillam will solely handle all Respiratory Care Board business. More ideas will be presented at the Board Retreat in March for consideration.

b) Legislative Session – Nothing to report.

c) Retreat Issues – Kevin Kinkade requested the Board to submit topic ideas by February 1, 2004.

d) Outside Counsel – Kevin Kinkade reported that a contract had been signed, orientation had been conducted December 1, 2003, and cases had been assigned for them to begin working on.

e) Contract Inspector – Kevin Kinkade reported that the first request for bids failed, and a second request for bids had been issued.

f) Contract Laboratory Services – Kevin Kinkade reported that this request for bids is currently open. A temporary contract is currently in use.

g) Presentation of Award – Kevin Kinkade presented Barbara Dunning a plaque in honor of her five years of service to the Missouri Board of Pharmacy.

#8 First DataBank, Inc., - Intern Training Pharmacy Application – Special Site – The Board reviewed an Intern Training Pharmacy Application for Special Site approval. **Gary Sobocinski made a motion to approve this facility for 500 hours, motion was seconded by Tim Koch. Motion passed 6:0:0:0, with roll call vote as follows:**

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

#9 Internship Study Status Report by Elaina Wolzak and Tim Koch – Tim Koch presented a verbal report on his work with the Dean on creating an email list, and that interns are confused concerning reporting hours to the school and to the Board. Elaina Wolzak presented a verbal report indicating that lack of responses to emails have been a problem. The interns are okay with school program, but feel the Board needs oversight to make sure they get a well-rounded program. Tim and Elaina agree to turn the intern training programs over to the schools, but Board must maintain oversight. It was determined that Board staff will conduct further NABLAW research concerning this issue, and the item will be discussed again at the Board’s Retreat meeting.

#10 Presentation to Outside Groups by Inspectors – Kevin Kinkade presented a summary of this issue. It was the Board’s consensus to table this matter.

#16 Children’s Mercy Hospital--Pediatric Clinical Pharmacology, Intern Training Pharmacy Application - Special Site - The Board reviewed an Intern Training Pharmacy Application for Special Site renewal. **Marty Michel made a motion to approve this facility for 750 hours, motion was seconded by Gary Sobocinski. Motion passed 6:0:0:0, with roll call vote as follows:**

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

The Board reviewed the following items in Section E that did not require individual action or discussion.

#13 2003 Strategic Plan
#13H Revised 2003 Strategic Plan

#14 **Motion Language for Rules/Amendments**

#15 **Long Term Care Discussion Notes, 8/6/03**

Recess Open 5:45 p.m.

Motion was made by Doug Lang and seconded by Gary Sobocinski to recess the open session meeting for the evening. Motion passed 6:0:0:0 with roll call vote as follows:

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

FRIDAY, DECEMBER 19, 2003

The Board reconvened in open session at 8:31 a.m. on December 19, 2003. All board members and staff were present as previously reported. It should also be noted that the following individuals were present on December 19, 2003:

Bert McClary, BNDD
Marilyn Taylor Williams, Director, Division of Professional Registration
Becky Kilpatrick, Counsel, Division of Professional Registration
Kyle Ludwig, University Hospital, Pharmacy Resident
Shannon Dobson, University Hospital, Pharmacy Resident
Dennis Hunt, Walgreens
Pam Marshall, Walgreens
Ron Fitzwater, Missouri Pharmacy Association
Kathy Browne, Missouri Pharmacy Association
Randy Meents, Missouri Pharmacy Association
Russell Andrews St. Luke's Hospital
Eric Geyer, Wal-Mart

#11 **Proposals for Rule Change:**

a) **4 CSR 220-2.100: Continuing Pharmacy Education** – Kevin Kinkade presented a verbal report on this proposed rule change. The Division is going to on-line renewals and the Board needs to re-evaluate how pharmacist continuing education is processed. Discussion was held. It was the Board's consensus to add "current and preceding reporting period".

Motion was made by Doug Lang that the Missouri Board of Pharmacy, based upon reasonably available empirical data including an assessment of the effectiveness and costs both to the state and to any private or public person or entity affected, hereby finds that the proposed amendment to 4 CSR 220-2.100 Continuing Pharmacy Education (with the revision as noted above) is necessary

to carry out the purposes of Section 338.010, 338.140, 338.210, 338.240, and 338.280, RSMo, authorizing the subject matter of the rule. Seconded by Tim Koch. Motion passed 6:0:0:0 with roll call vote as follows:

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

b) **4CSR 220-2.020: Pharmacy Permits** - Kevin Kinkade presented a verbal report on this proposed rule change. The Attorney General's Office suggests a temporary license versus a grace period when a change of ownership occurs. Discussion was held. **Motion was made by Doug Lang that the Missouri Board of Pharmacy, based upon reasonably available empirical data including an assessment of the effectiveness and costs both to the state and to any private or public person or entity affected, hereby finds that the proposed amendment to 4 CSR 220-2.020 is necessary to carry out the purposes of Section 338.010, 338.140, 338.210, 338.240, and 338.280, RSMo, authorizing the subject matter of the rule. Seconded by Barbara Dunning. Motion passed 6:0:0:0 with roll call vote as follows:**

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

c) **4CSR 220-5.020: Drug Distributor Licensing Requirements** - Kevin Kinkade presented a verbal report on this proposed rule change. The Attorney General's Office suggests a temporary license versus a grace period when a change of ownership occurs. **Motion was made by Doug Lang that the Missouri Board of Pharmacy, based upon reasonably available empirical data including an assessment of the effectiveness and costs both to the state and to any private or public person or entity affected, hereby finds that the proposed amendment to 4 CSR 220-5.020 is necessary to carry out the purposes of Section 338.010, 338.140, 338.210, 338.240, and 338.280, RSMo, authorizing the subject matter of the rule. Seconded by Barbara Dunning. Motion passed 6:0:0:0 with roll call vote as follows:**

Barbara Dunning – yes	Doug Lang – yes	Anita Parran – yes
Marty Michel – yes	Tim Koch – yes	Gary Sobocinski – yes

d) **4CSR 220-5.030: Definitions and Standards for Drug Wholesale Pharmacy Distributors** - Kevin Kinkade presented a verbal report on this proposed rule change. Discussion was held. It was the Board's consensus to research for a better term for "discounted or below-wholesale costs", possibly could use "own use."

Motion was made by Doug Lang that the Missouri Board of Pharmacy, based upon reasonably available empirical data including an assessment of the

effectiveness and costs both to the state and to any private or public person or entity affected, hereby finds that the proposed amendment to 4 CSR 220-5.030, with the following revisions

- delete the last sentence,
- approve the first sentence,
- proposal also rescinds (10),

is necessary to carry out the purposes of Section 338.010, 338.140, 338.210, 338.240, and 338.280, RSMo, authorizing the subject matter of the rule. Seconded by Marty Michel. Motion passed 6:0:0:0 with roll call vote as follows:

Barbara Dunning – yes
Marty Michel – yes

Doug Lang – yes
Tim Koch – yes

Anita Parran – yes
Gary Sobocinski – yes

#12 **DEA Notice of Proposed Rulemaking – Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities, FedReg Vol. 68, No 212 — Nov. 3, 2003, pp 62255-62259** – Susan McCann and Bert McClary presented a summary of this matter and provided proposed language to 4 CSR 220-2.900.

Discussion with the Board and members of the public was held. It was the consensus of the Board to report ideas for the comment letter to DEA about the proposed rules to Kevin Kinkade by the close of business December 23, 2003. In addition, it was the Board's consensus to wait for DEA to finalize their rule(s) on this subject before the Board proceeds to change its rule(s).

#7 **Proposed 2004 Legislation - MPA's Preliminary Draft of Changes to Pharmacy Practice Act** – Kevin Kinkade presented a verbal report on this matter, and provided a comparison of both proposals. Discussion was held concerning the following particular sections of the legislation:

338.013 – The difference in the two proposals is that MPA takes out the legal work age requirement. MPA provided the reason that family-owned pharmacies need to be able to hire their children. Tom Glenski addressed their concerns about notifying them of exceptions to state and federal labor laws allowing this. President Wolzak reiterated the need to make decisions today; MPA stated that theirs is a work in process and will not be able to make final decisions today.

338.055 – The difference in the two proposals is that the Board proposes last Section 7. MPA's is a referral section that refers to injunction and uses the word "shall" giving no leeway to the Board to use discretion. The Board iterated its reasons for wanting Section 7, it is a public safety issue; legislatures, current and past Board members are concerned about having no authority to take quick action. MPA provided their concern about Section 7; they want an independent entity to approve the suspension, there is too much harm to small business if they are shut down and the Board is overruled by the Administrative Hearing Commission. Research should be done to determine if the Attorney General's Office could be the independent entity.

338.075 – This is in the Board’s proposal, but not MPA’s. The Board iterated that this is strictly for unlicensed activity, MPA stated that their legal counsel advised against this section.

338.145 – The difference in the two proposals is that MPA adds a majority vote of the Board. MPA stated that more people than just the Board President should be involved in the decision. The Board reiterated that this is just for unlicensed activity.

338.155 – This is in both proposals, MPA added paragraph 4. Ron Smith reported that “state indemnifying” is not necessary. MPA reported that their legal counsel recommended it. It was the Board’s consensus to agree to add paragraph 4 without the words “indemnify and” of the MPA proposal. Ron Smith is to research further.

338.353 – This section is tied to 338.055.7, and depends on what is left in 338.055.7.

338.380 – This is in the Board’s proposal, but not MPA’s version. Kevin Kinkade reported that this section and subpoena are the most important issues of this legislation. MPA stated their concerns involving “misbranding” is too broad, and it is generally too broad overall. The Board will research the definitions of “misbranded.”

338.390 – This is in the Board’s proposal, but not MPA’s version. MPA voiced concerns that future administrations may use this to try to fund the Board of Pharmacy, their legal counsel states that this may be reason for someone not wanting to go to the AHC.

338.059 – MPA added “USP approved container.” MPA reiterated their concerns that dentists and other practitioners are not using appropriate packaging. The Board recommended changing the wording to “as defined by USP.”

338.140 – MPA added this section. It was the Board’s consensus that this section gives them no more authority than it already has.

338.155 – Ron Smith stated that it should be taken out with the exception of “AG to defend.”

338.175 – Board has concerns about sentence limiting to only four projects, Board suggested taking that sentence out of this section.

338.010 – Board agreed with collaborative practice wording.

MPA will try to have a meeting on December 29, 2003, and will have a response to Kevin Kinkade later that day. Board will plan a conference call for December 30th.

MPA discussed their idea of using legislation similar to the Dental Board’s on the subject of impairment. The Board would like more information and wants to see other practice acts and how these programs work. Board agreed that this is a place to start. The Board will participate in MPA’s task force on this issue.

Marilyn Taylor Williams addressed those attending the meeting. She stated she is glad to see everyone working together, and hopes everyone will keep the communication lines open. She is committed to helping with this legislation.

Discussion of letter to licensees and legislatures. It was the Board’s consensus to table this matter to the December 30th conference call, but have redraft done for legislatures.

Motion to Adjourn 12:15 p.m.

At 12:15 p.m. Marty Michel made a motion to adjourn the meeting, seconded by Doug Lang. Motion passed 6:0:0:0 with roll call vote as follows:

**Barbara Dunning – yes
Elaina Wolzak – yes**

**Doug Lang – yes
Tim Koch – no**

**Anita Parran – yes
Gary Sobocinski – yes**

**KEVIN E. KINKADE, R. Ph.
EXECUTIVE DIRECTOR**

DATE APPROVED: _____