

OPEN MINUTES

STRATEGIC PLANNING MEETING Missouri Board of Pharmacy

April 20-21, 2011
Hilton Garden Inn
3300 Vandiver Drive
Columbia, MO

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed at the meeting. The regular meeting was called to order by President James Riddle at 8:04 a.m. on April 20, 2011, at Hilton Garden Inn, Columbia, Missouri. The Strategic Planning portion of the open meeting began at approximately 4:17 p.m. on April 20, 2011.

Board Members Present

James Riddle, R.Ph., President
Barbara Bilek, R.Ph., Vice President
Janine Burkett, R.Ph., Member
Pamela Marshall, R.Ph., Member
Anita Parran, Public Member

Board Members Absent

Melissa Graham, R.Ph., Member

Staff Present

Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
George McConnell, R.Ph., Inspector
Andi Miller, R.Ph., Inspector
Steven Smith, R.Ph., Inspector
Dan Vandersand, R.Ph., Inspector
Frank VanFleet, R.Ph., Inspector
Sid Werges, R.Ph., Inspector
Barbara Wood, Inspector
Tammy Siebert, Executive I

Others Present

Curtis Thompson, Legal Counsel
Visitors as recorded in the visitor register

3. **2011 Legislation** - Discussion requested on any legislative changes the Board would like to propose for the 2011-2012 legislative session.

8. **Automated/Remote Dispensing Classification** – See attachment (20 CSR 2220-2.900). The Board should consider creating a new class for the permits for remote dispensing systems in licensed health care facilities and ambulatory care settings as required by 20 CSR 2220-2.900 Automated Dispensing and Storage Systems. This will be a proactive approach since we currently have no systems licensed with us; however, there has been an increase in interest in using these systems at LTC facilities. Currently, an applicant would have to apply as a Class C: Long Term Care pharmacy for a system at a LTC facility but we have no way to distinguish it from a typical Class C pharmacy. A separate class will also allow us to revise the rule exempting a remote system from certain pharmacy requirements that are not necessary, for example, the water/sink requirement, drug reference. This would also allow us to revise the rule stating no other type of pharmacy activity can occur there. The same issues apply for a remote system used in an ambulatory care setting that would currently have to license as a Class A. Since these will not be your typical pharmacy we should have a class that distinguishes them from our typical pharmacy classes.

Discussion was held regarding creating a new classification for pharmacy permits for remote dispensing. It was Board consensus for office staff to draft legislative language for this new classification for review at the July meeting.

4. **Compounding for Office Use** – Discussed in the regular open session meeting.

5. **Electronic Records** – Discussed in the regular open session meeting.

6. **Drop Sites** - See #D15 open agenda materials.

The Board asked to review other state laws regarding drop sites. Would the Board like to proceed with any statutory or regulatory changes?

Discussion was held. It was Board consensus that “drop sites” need to be defined. Sam Leveritt commented that retirement communities prefer to have medications delivered. Pam Marshall suggested that a log be kept to document who has the prescription, and suggested that a written offer to counsel patients must be attached to the package, and HIPPA-approved packaging be used for this type of delivery.

Tom Glenski commented this may require a statutory change; we currently refer to Section 338.210. Kim Grinston commented it could possibly be handled by regulation rather and statutorily.

Doug Lang commented concerning drugs that are required to be delivered to physician offices and administered at the doctor’s office. Tom Glenski clarified the problem is that the prescription is being delivered somewhere for the patient to pick up. Mr. Lang also mentioned problems when patients want their drugs delivered to a vacation hotel

location. Pam Marshall also commented about the patient's relative that picks up the patient's prescription and delivers it to the patient's neighbor. Steve Smith pointed out homeless individuals don't have a home to which to deliver prescriptions.

It was Board consensus for office staff to begin drafting proposed rule language for this topic.

9. Nuclear Pharmacy

Would the Board like to proceed with any regulatory changes?

Sam Leveritt of Cardinal Health presented information about delivery of medications to patients, emergency rooms, etc; compounding for office use; requiring his type of pharmacy to be licensed as a drug distributor conflicts with federal regulation; stated he wished he had been included in the technician working group; Missouri is only state that indicates "physician use only" instead of "per physician's order." All these items directly affect the nuclear pharmacy field and should be specifically addressed; he's asking for more regulation specific to nuclear pharmacy practice. Pam Marshall asked how many nuclear pharmacies are located in Missouri; Mr. Leveritt reported he believes there are 8-10.

MOTION TO CLOSE 5:10 PM

At 5:10 p.m. Anita Parran made a motion, seconded by Janine Burkett, that the Board go into the closed session regular meeting 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 324.001.8, RSMo. Motion passed, all in favor, none opposed, Melissa Graham absent.

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 5:10 PM.

THURSDAY, APRIL 21, 2011

RECONVENED OPEN

By motion duly made, seconded, passed and recorded in closed session minutes, the Board reconvened in open session at 2:28 p.m. on Thursday, April 21, 2011. All Board members, staff and Curt Thompson were present as previously recorded.

MEMBERS OF THE PUBLIC RETURNED TO THE MEETING ROOM AT 2:29 PM.

7. Regulation of Device Distributors – Section 338.315, RSMo

Given our current statutory authorization, should device distributors be exempt from Board regulation?

Kim Grinston reported and discussion was held. **Motion was made by Barbara Bilek, seconded by Pam Marshall, to not require device-only distributors to be licensed in Missouri due to statutory ambiguity. Motion passed, all in favor, none opposed, Melissa Graham absent.**

9. Nuclear Pharmacy

President Riddle suggested Sam Leveritt form and lead an industry task force regarding nuclear pharmacy to get a general consensus/view of new/revised regulations.

10. Generic Substitution – Section 338.056, RSMo.

Should the Board consider additional language or clarification to make things more efficient for pharmacies and reduce calls to prescribers. [Recommended by Jan Burkett]

Janine Burkett reported concerning the need to call the prescriber when a prescription is not clear, especially if the prescriber is writing for a dispense as written prescription and the drug is no longer available. Discussion was held. It was Board consensus for office staff to review and report back at a future meeting.

11. Take-Back Programs – Section 338.315, RSMo

Should the Board proceed with statutory/regulatory changes on returning prescriptions to a pharmacy? [Recommended by Jim Riddle]

President Riddle commented and discussion was held. Kim Grinston reported the federal government has not yet made a change, and suggested the Board consider making a statutory change to allow us authority to create regulations after the federal government makes a decision. It was Board consensus to proceed with a statutory change.

12. 20 CSR 2220-1.010 – Discretionary Authority/Inspection Responses

Kim Grinston reported and discussion was held. Barbara Bilek suggested that 30 days be changed to 45 days in (9). Further discussion was held. **Motion was made by Barbara Bilek, seconded by Janine Burkett, to proceed with the amendment to 20 CSR 2220-1.010 as noted. Motion passed, all in favor, none opposed, Melissa Graham absent.**

13. Well-Being Request For Proposal – See closed agenda attachment.

Kim Grinston reported and discussion was held. Barbara Bilek suggested office staff check with other boards' existing well-being programs to see if our licensees could participate in their already established program. Ron Fitzwater commented the Missouri Pharmacy Association still gets some interest and the MPA leadership is still interested in such a program, but they want it done correctly. It was Board consensus that it is also still interested in pursuing, but additional information is needed before a decision can be made. It was Board consensus to obtain additional information.

14. 2009 and 2010 Annual Report Drafts

Motion was made by Anita Parran, seconded by Barbara Bilek, to approve the 2009 Annual Report as printed. Motion passed, all in favor, none opposed, Melissa Graham absent.

Motion was made by Anita Parran, seconded by Barbara Bilek, to approve the 2010 Annual Report as printed. Motion passed, all in favor, none opposed, Melissa Graham absent.

15. **Approval of Minutes**

- September 24-25, 2008 Regular Meeting

Motion was made by Barbara Bilek, seconded by Pam Marshall, to approve the September 24-25, 2008, open session regular meeting minutes as printed. Motion passed, all in favor, including James Riddle; none opposed, Anita Parran and Janine Burkett abstained, Melissa Graham absent.

- November 18, 2008 Regular Meeting

Motion was made by Barbara Bilek, seconded by Pam Marshall, to approve the November 18, 2008, open session regular meeting minutes as printed. Motion passed, all in favor, including James Riddle; none opposed, Janine Burkett abstained, Melissa Graham absent.

- January 28-29, 2009 Regular Meeting

Motion was made by Barbara Bilek, seconded by Anita Parran, to approve the January 28-29, 2009, open session regular meeting minutes as printed. Motion passed, all in favor, including James Riddle, none opposed, Janine Burkett abstained, Melissa Graham absent.

1. **Patient Safety and Just Culture**

Kim Grinston reported.

2. **Compliance Initiative**

- A. Compliance Is Key
- B. Assessment Draft
- C. Compliance Plans

Kim Grinston reported about various educational resources already/to be made available to licensees, including a webinar presented by Tom Glenski in July and another near the beginning of the flu season. Ms. Grinston reported a self-assessment form has been drafted and provided to the inspectors for their review and input. Ms. Grinston also reported about more effective use of the Board's newsletters as a way to promote awareness. She plans to incorporate a "best practices" section into the newsletter.

Kim Grinston reported regarding compliance action plans, and asked for Board approval to pursue the educational resources and self-assessment form. She stated she plans to have them available in July and the compliance action plans will be provided to the Board for approval at the July meeting. Several Board members complimented Ms. Grinston on her presentation and fully agreed it will be a great asset for the Board.

Ron Fitzwater of MPA offered to help make the information available to their members and to the public.

THE BOARD ADJOURNED THE 2011 OPEN SESSION STRATEGIC PLANNING MEETING AND RETURNED TO THE REGULAR OPEN SESSION MEETING AT 3:45 P.M.

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 7/11/12