

**OPEN MINUTES**  
**Missouri Board of Pharmacy**  
**Hospital Advisory Committee Meeting**

**February 24, 2016**

The Missouri Hospital Advisory Committee 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.

**Committee Members Present**

Bert McClary, R.Ph., Chairman  
Daniel Good, R.Ph., Member  
James Gray, R.Ph., Member  
Colby Grove, R.Ph., Member  
Kevin Kinkade, R.Ph., Member  
Neil Schmidt, R.Ph., Member  
Greg Teale, R.Ph., Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Katie DeBold, Inspector

**Others Present**

Barbara Bilek, Board Member  
Christian Tadrus, R.Ph., Board Member  
Sarah Wilson, Missouri Hospital Association  
Julie Creach, Missouri DHSS

Chairman McClary opened the meeting at 8:34 a.m. and introductions of attendees were made. Sarah Wilson was introduced as the new Vice-President of Clinical and Regulatory Affairs for the Missouri Hospital Association (MHA). Daniel Good and Colby Grove joined the meeting at approximately 8:44 a.m. Mr. McClary announced Colby Grove has been appointed to the Committee as the official Missouri Pharmacy Association representative. Mr. Grove introduced himself and indicated he is currently employed by Walgreens pharmacy.

**Agenda Item # 1:** The Committee reviewed the suggested Board changes to the proposal included in the agenda materials. James Gray asked if the proposal should reference USP Chapter 795. Bert McClary indicated it was a good suggestion but may need further vetting/discussion. Committee consensus to inform the Board that the suggested changes were reviewed by the Committee and no objections were raised.

**Agenda Item # 2 & #3:** Bert McClary indicated these items would be discussed on the March 2016 conference call.

**Agenda Item # 4:** Bert McClary indicated the Board of Pharmacy and DHSS hosted a webinar in conjunction with MHA after SB 808 was enacted to provide additional compliance information, however, the recording of the webinar was lost due to technical issues. Tom Glenski reviewed the slides during the meeting from the original webinar. Additionally, the following discussion was held:

- Tom Glenski commented that the “licensed hospital” generally does not include entities on the same campus or under the same provider number unless considered as part of the hospital license by DHSS. A question was raised regarding multi-purpose licenses. Mr. Glenski indicated multi-purpose licenses are generally considered as one hospital unless determined otherwise by DHSS. Bert McClary provided additional history on the definition of the hospital premises and indicated nursing homes and long-term units could be included under the hospital license if they are named with DHSS as part of the hospital premises.
- Tom Glenski discussed the Class B/drug-distributor license exemption language in SB 808 and indicated the Board’s revised drug distributor rule is somewhat broader. Mr. Glenski indicated the drug distributor exemption only applies to medication leaving the hospital and does not exempt facility shipments to the hospital. Bert McClary asked about distributions within a campus to an ambulance service that may be owned by a separate party. Tom Glenski indicated distributions to separately owned ambulance services may not qualify for the exemption. Mr. McClary indicated the previous policy was that supplying an ambulance service was not considered distribution to an outside entity if the ambulance service was based out of the hospital. Mr. McClary also suggested dispensing to an ambulance service could be considered emergency dispensing. Further discussion was held. Neil Schmidt asked if this issue raised Robinson-Patman concerns.
- Tom Glenski discussed the definition of inpatient dispensing and generally defined it as a drug prepared and administered to a patient within the DHSS licensed hospital premises regardless of billing status. Further discussion was held. Mr. Glenski reported SB 808 would now allow both inpatient and outpatient dispensing at the same location. Barbara Bilek and Neil Schmidt indicated current 340(B) requirements may impact commingling of inpatient and outpatient dispensing.
- Tom Glenski indicated the Class B pharmacy area would generally consist of the area inspected by the Board during the initial inspection and indicated the expanded Class B language would allow qualifying satellite pharmacies to be licensed as a Class B pharmacy.
- Bert McClary asked if additional rule language should be developed to address satellite pharmacies or instances where pharmacists are used to assist in dispensing in auxiliary locations such as infusion clinics, physician clinics and hospital emergency departments when pharmacy services are not available. Barbara Bilek indicated CMS may require pharmacist participation in these

alternative locations which can be complicated under current Board rules. Greg Teale strongly suggested that the Committee and the Board consider accommodating infusion clinics as the current regulatory environment has become a significant challenge. Mr. Teale indicated the Board should encourage pharmacist participation in these settings to protect the public. At a minimum, Mr. Teale, Neil Schmidt and Barbara Bilek suggested aligning the Board's rules/statutes with current DHSS, Joint Commission and CMS standards. Bert McClary asked that staff add the regulation of satellite pharmacies/alternative hospital practice settings to a future agenda for additional discussion and suggested the Committee could be instrumental in educating the Board about the unique differences in hospital practice. Committee members also asked that the Board clarify what is the pharmacy permit area.

- Tom Glenski indicated he's been asked about access to a Class B pharmacy by other practitioners and indicated these practitioners may need to be registered as technicians. Bert McClary and James Gray indicated this may not be practical for hospitals and asked how the language could be amended to accommodate hospital practice. Tom Glenski suggested that Committee Members draft rule language for the Board's review.
- Bert McClary asked about automated dispensing systems in the emergency department that may be used to provide patient take home medications. Mr. McClary suggested there may be two options: (1) conduct the activity under full Board regulation/licensure or (2) treat this activity as an extension of medication administration and address it as a take-home medication supply cart that is accessed by physicians and nurses. Tom Glenski remarked these systems are not set-up as pharmacy supervised systems and asked if this was really physician dispensing. Tom Glenski questioned the amount of medication allowed and suggested that DHSS rules may prohibit dispensing a full course of therapy.
- Discussion was held regarding the current medication therapy services (MTS) requirements. Greg Teale suggested that the Committee review the MTS requirements for infusion clinics. Jim Gray suggested revising the current rule to allow a single group MTS protocol when MTS is done under the technical hospital system but not on the hospital premises. Mr. Teale asked if an advanced practice provider can initiate an MTS protocol. James Gray indicated the current statute only allows initiation by a physician. Questions were also raised regarding MTS services by contracted staff. Bert McClary suggested possibly developing a future MTS guidance document. Mr. McClary also indicated CMS has issued guidance on non-physician privileging/credentialing issues.
- Committee consensus to consider a potential rule for Class B hospital related issues. Bert McClary suggested reviewing the following issues as part of the rule consideration: (1) remotely located infusion centers and the current restrictions on filling/distributing orders, (2) emergency department dispensing, (3) access to clinic pharmacies by nursing staff and (4) an exemption that would allow drug distribution from other hospital related locations/clinics.

- Tom Glenski asked the MSHP representative to solicit webinar questions from MSHP's membership. Tom also cautioned attendees that some offsite Class B pharmacies are using their internal ordering system to dispense controlled substances. Mr. Glenski cautioned that hospitals would need to follow DEA rules on electronic ordering.

**Agenda Item # 7 & # 8:** The following future topics were suggested by Board members: regulation of pharmacy technicians within a hospital, SB 808 implementation issues, state regulation of infusion centers and special rules for Class B pharmacies. Additionally, the following discussion was held on the regulation of pharmacy technicians:

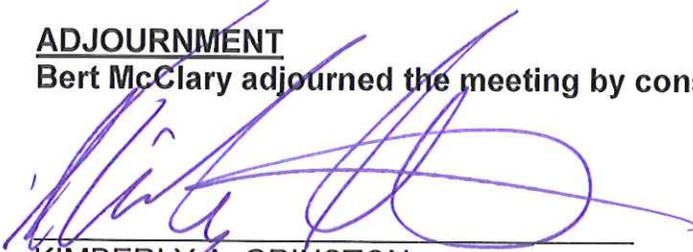
- Christian Tadrus asked for suggestions on participants for the Board's pharmacy technician working group. Mr. Tadrus indicated community pharmacies are not opposed to discussing technician qualifications but indicated significant questions still remain about feasibility/value of potential approaches. James Gray commented on advances in remote supervision and suggested leveraging technology to more fully utilize pharmacist expertise. Mr. Gray also commented remote technician supervision may not be appropriate in community pharmacy at this time but may be ripe for hospitals. Barbara Bilek cautioned small hospitals would have to afford the Board's decision regarding remote/electronic supervision. James Gray suggested a rule could provide a clearer path for leveraging technology when operating within an organized healthcare system. Greg Teale suggested that the committee consider a tech-check-tech proposal and indicated this would significantly advance efficiency and operational processes in hospitals.
- Christian Tadrus asked the Committee what technician qualification standards are needed to protect the public. Kimberly Grinston indicated the topic was discussed in a recent state regulator meeting where it was suggested that technician certification was a way to ensure a quality job market. Barbara Bilek indicated technician certification does not guarantee a better work ethic.
- Sarah Wilson asked if pharmacy technicians fall under the unlicensed assisting personnel (UAP) rules. Bert McClary indicated it was unlikely because 25% of their activities may not be directly related to patient care. Greg Teale indicated some hospitals may be using unregistered technicians in parts of the hospital under DHSS' authority. Bert McClary suggested this should not be an acceptable practice.
- Additional discussion was held regarding final verification by a pharmacist of patient orders. James Gray indicated final pharmacist verification may not be happening in some critical access hospitals with limited staff. Neil Schmidt asked about hospitals with drug rooms. Greg Teale indicated other states are using technology to allow alternative means of pharmacist supervision and verification. Mr. Teale specifically indicated Wisconsin allows technicians to dispense chemotherapy products with a pharmacist remotely supervising and signing off on their work. Mr. Teale suggested that Missouri should be progressive and

consider similar models. Bert McClary cautioned against expanding technician duties/roles until the training issues are addressed.

The Committee agreed to meet via conference call on March 2, 2016, and again in Jefferson City on April 11, 2016.

**ADJOURNMENT**

**Bert McClary adjourned the meeting by consensus at approximately 2:36 p.m.**



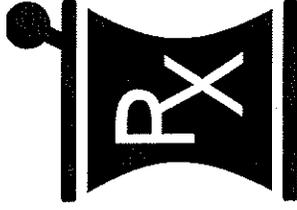
---

KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved: 05/06/2016

# **A Review of Senate Bill 808 and the Revised Class B Hospital Pharmacy Permit**

**Missouri  
Board of Pharmacy**



**Missouri  
Department of Health  
and Senior Services**

January 23, 2015

# Presenters

## Missouri Board of Pharmacy

- Kimberly Grinston, J.D. – Executive Director
- Tom Glenski, R.Ph. – Chief Inspector

## Missouri Department of Health and Senior Services

- Dean Linneman, - Deputy Division Director  
Division of Regulation and Licensure

# Program Objectives

- Review Senate Bill 808 effects on the practice of pharmacy in hospital settings
- Explain the revised Class B Hospital Pharmacy permit
- Answer related questions

No pharmacy continuing education credit is being offered for this program

# How to Ask a Question

File View Help

Audio

Telephone

Mic & Speakers

Dial: +1 (484) 589-1010

Access Code:

**Audio PIN:**

If you're already on the call, press #47# now.

Talking: Missouri Board of Pharmacy

Questions

Missouri Board of Pharmacy  
"Creating A Culture of Compliance"

[Enter a question for staff]

Send

Creating A Culture of Compliance: Compliance Keys For The Pharmacist-in-Charge & Pharmacy Managers/Supervisors

Webinar ID: 521-928-430

**GoToWebinar**



# SB 808

- Revised Class B Hospital ~~Outpatient~~ Pharmacy
  - Owned, managed or operated by a hospital
  - Includes pharmacy located in a clinic or facility under common control, management, or ownership of the same hospital or hospital system

# SB 808

## Definitions:

- "Hospital", a hospital as defined in section 197.020
- "Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system

# SB 808

- Does not change jurisdiction of either DHSS or BOP within a hospital
- Hospital pharmacies solely providing drugs for patients within the hospital still require no BOP license
- Joint rulemaking between DHSS and BOP governing medication distribution and MTS by a pharmacist within a hospital
- Gives BOP authority to investigate complaints about individual BOP licensees within a hospital

# **SB 808**

- Require BOP MTS certificate for pharmacists performing MTS within hospital
- No BOP drug distributor license required to distribute drugs from Class B permit to hospital clinic or facility for patient care

# SB 808

- Allows prescription labeling by unique identifier instead of sequential number
- Allows use of orders versus prescriptions by Class B pharmacy
  - Did not address generic substitution of such orders
  - Seek guidance from your legal counsel concerning substitution

# SB 808

**"Medication order"**, an order for a legend drug or device that is:

- (a) Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee; and
- (b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;

**"Patient"**, an individual receiving medical diagnosis, treatment, or care at a hospital or a hospital clinic or facility.

# SB 808

Creation of advisory committee to review and make recommendations to all BOP/DHSS joint rules

- Seven members, designated by
  - MHA (2)
  - MSHP (1)
  - MPA (1)
  - DHSS (2)
  - BOP (1)
- BOP awaiting designations

# Class B Hospital Pharmacy

- No longer limited to DHSS licensed premise
- Can be off-site hospital clinic or facility
- Can use orders instead of two-line prescription
- Can use hospital's order numbering system
- For distributions to hospital clinics and facilities, if exceed 5%, no drug distributor license required

# “Inpatient” vs. “Outpatient”

- Various meanings
- Avoid use of terms
- BOP jurisdiction interpretation:
  - A drug prepared within and administered to a patient within the DHSS licensed hospital premises (regardless of patient billing status):  
**DHSS jurisdiction**

# QUESTIONS

# Questions-Licensure

What areas are currently included in a DHSS hospital license and how can a hospital determine this?

# DHSS Licensed Premises

197.60.2

Each license shall be issued only for the premises and persons or governmental units named in the application, and shall not be transferable or assignable except with written approval of the department of health and senior services....(1953)

# DHSS Licensed Premises

197.052

An applicant for or holder of a hospital license may define or revise the premises of a hospital campus to include tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way. (2010)

# DHSS Licensed Premises

## Rule Revision Draft Language:

Hospital definition:

(A) Building(s):

- (1) Constructed to hospital standards as outlined in 19 CSR 30-20.030;
- (2) Identified on the hospital's license application as part of the facility;
- (3) Devoted primarily for the diagnosis, treatment, or care for not less than twenty-four (24) consecutive hours in any week of three (3) or more nonrelated individuals suffering from illness, disease, injury, deformity or other abnormal physical conditions, or devoted primarily to provide for not less than twenty-four (24) consecutive hours in any week medical or nursing care for three (3) or more nonrelated individuals;

(B) The term "hospital" does not include convalescent, nursing, shelter or boarding homes as defined in chapter 198, RSMo.

# DHSS Licensed Premises

Rule Revision Draft Language:

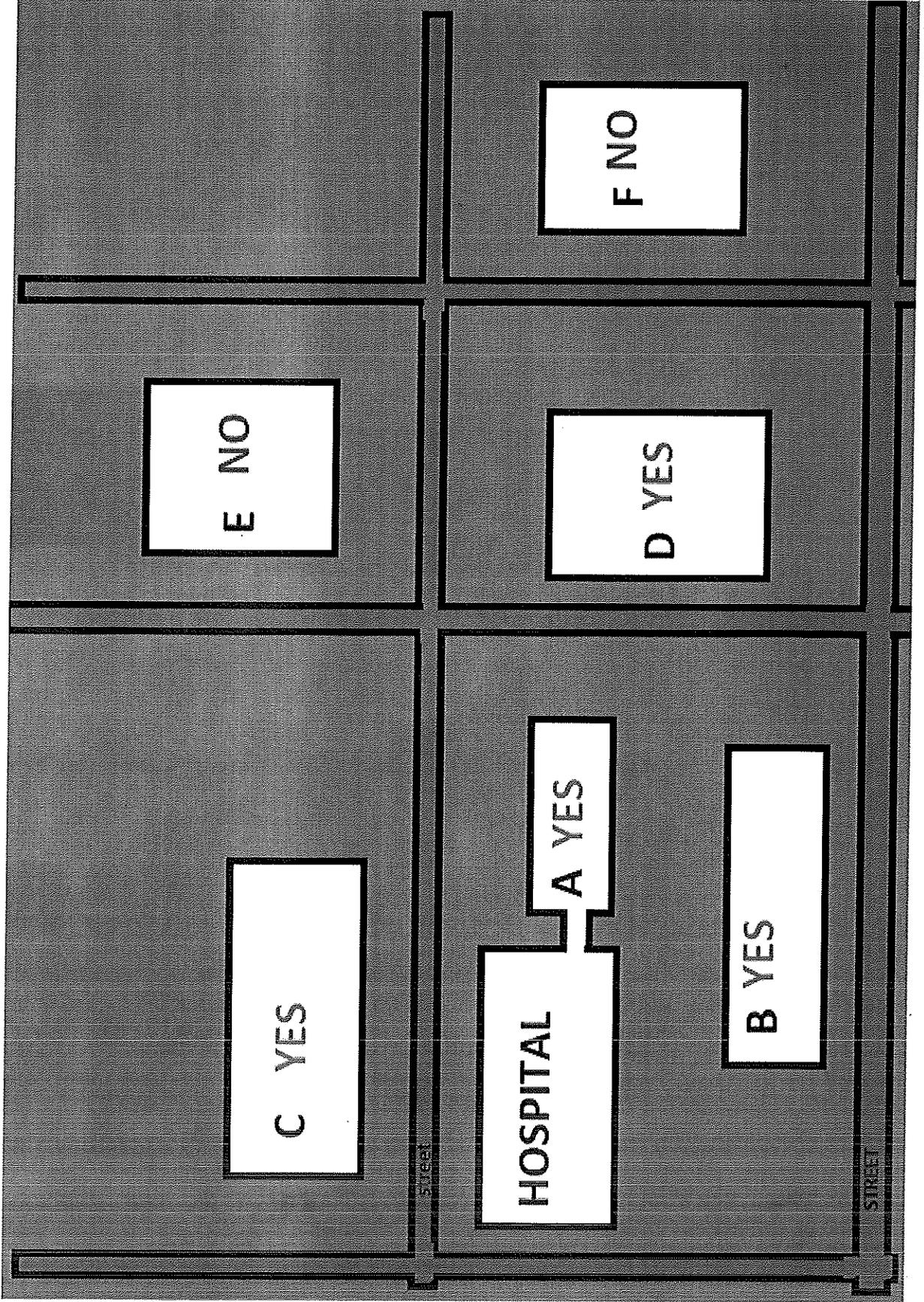
Hospital premises:

- (1) Buildings located on tracts of property which are adjacent to the hospital but for a common street or highway and its accompanying right-of-way may be included in the hospital's license if they meet subsection (A)(1) - (2) above.

# DHSS Licensed Premises

- Premises ≠ Hospital campus
- Premises ≠ Hospital system
- Premises ≠ Corporate structure
- Premises ≠ CMS Certification Number (CCN)
- Premises ≠ Patient billing status
- Premises ≠ Provider employment status
- Premises ≠ Other DHSS license (ASC, LTCF)
- Premises ≠ Space rented to other entity

# Possible License Scenarios



# Questions-Licensure

How can a hospital determine if a clinic, infusion center or other non-inpatient area qualifies for a Class B license?

# Statutory Definition

- 338.165
- "Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system
- Seek legal guidance in determination, especially for joint ownership or private entity lease

# Questions-Licensure

What defines the Class B “licensed area” in a hospital pharmacy, and can a hospital include more than one “area” in a Class B license?

# Questions-Licensure

Are there any restrictions on mixed inpatient/outpatient activities or use of common stock for inpatient/outpatient orders/prescriptions in a Class B inpatient pharmacy?

# Questions-Licensure

What defines the Class B licensed area in a clinic, and are there restrictions on access by other licensed practitioners?

# Questions-MTS

Is a MTS certificate required for a pharmacist to perform routine inpatient “medication order management” procedures?

# Statutory Requirement

338.165

4. All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board.

# Questions-MTS

Can non-employee pharmacists be authorized for hospital MTS protocols, e.g. pharmacists providing remote pharmacy order review and other clinical pharmacy services, including out-of-state pharmacists?

# Remote Order Verification

- Pharmacist located in Missouri
  - Hold MO pharmacist license
  - If working outside of pharmacy or hospital, must comply with 20 CSR 2220-2.6055 *Non-Dispensing Activities*
- Pharmacist located outside of Missouri
  - Pharmacist must hold MO pharmacist license, or
  - Must be working in pharmacy holding MO non-resident permit
- Class J is not required on the pharmacy permit
- Remote supervision of technicians is not allowed

# Questions-MTS

When is credentialing and privileging required for MTS protocols?

# Questions-MTS

Can the same MTS protocols be used for both inpatients and outpatients?

# **BOP MTS Regulation**

20 CSR 2220-6.060; 6.070; 6.080

## **Requirements**

- General
- Physician
- Protocol
- Drug modification
- Recordkeeping

# Questions-Drug Distribution

Can a hospital that has a Class B license distribute freely between all facilities within the health system?

# Questions-Drug Distribution

Can a hospital that does not have a Class B license or drug distributor license distribute to a hospital-owned clinic or fill medication orders for another hospital owned by the same health system?

# Questions-Rules

What will be the process for developing and promulgating the new joint rules?

# Questions-Rules

When will the Joint Rule Making Committee be appointed?

# Questions-Rules

When will the proposed DHSS hospital pharmacy services rules be sent to the Secretary of State for publication as proposed rules?

# **QUESTIONS FROM PARTICIPANTS**

# How to Ask a Question

File View Help

Audio

Telephone

Mic & Speakers

Dial: +1 (484) 589-1010

Access Code:

**Audio PIN:**

If you're already on the call, press #47# now.

Talking: Missouri Board of Pharmacy

Questions

Missouri Board of Pharmacy  
"Creating A Culture of Compliance"

[Enter a question for staff]

Send

Creating A Culture of Compliance: Compliance  
Keys For The Pharmacist-in-Charge &  
Pharmacy Managers/Supervisors

Webinar ID: 521-928-430

**GoToWebinar**

