

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

January 23, 2015

## 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

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

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Board of Pharmacy**



**Missouri  
Department of Health  
and Senior Services**

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# Presenters

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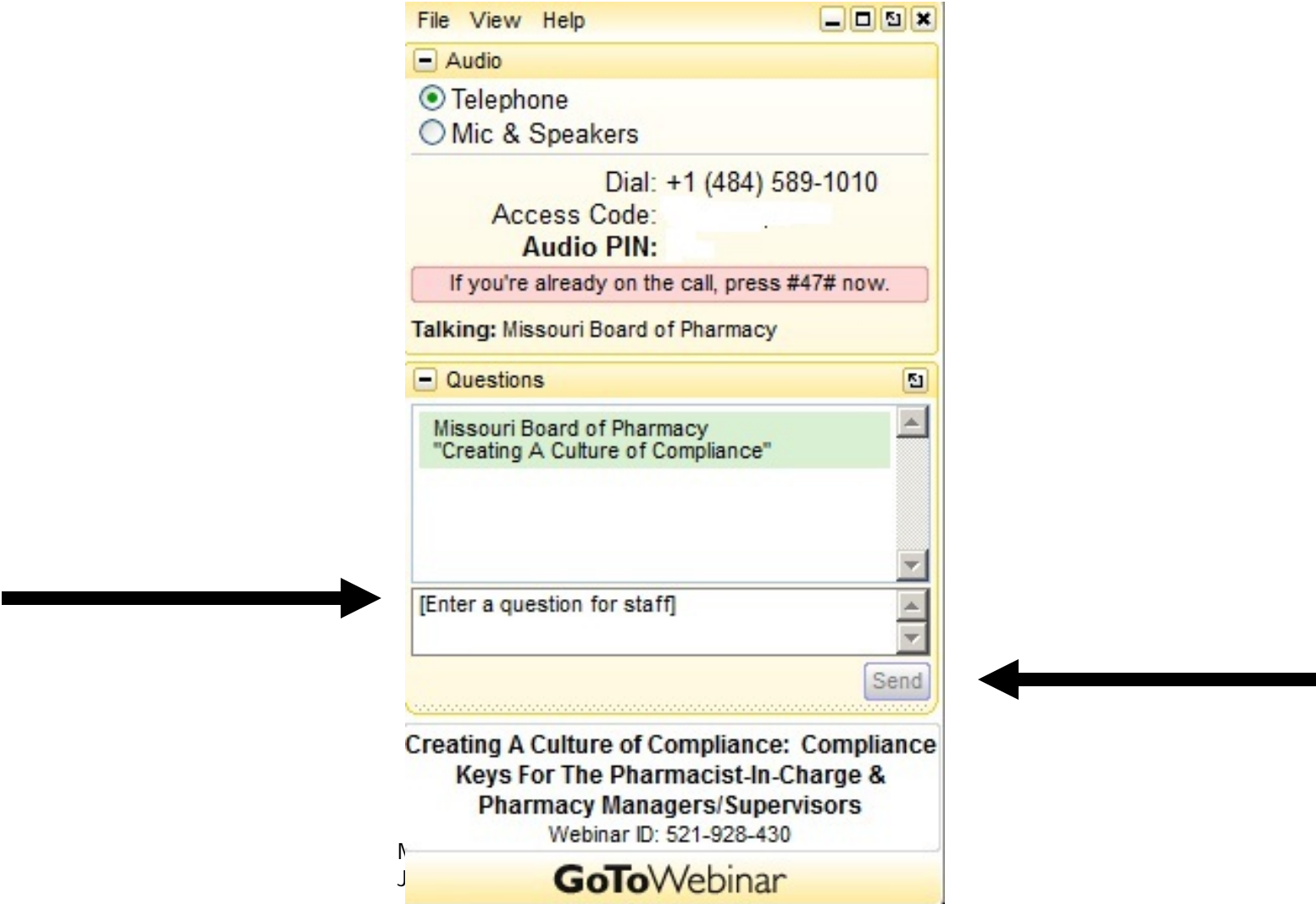
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# Program Objectives

- 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



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Creating A Culture of Compliance: Compliance  
Keys For The Pharmacist-In-Charge &  
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# 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:

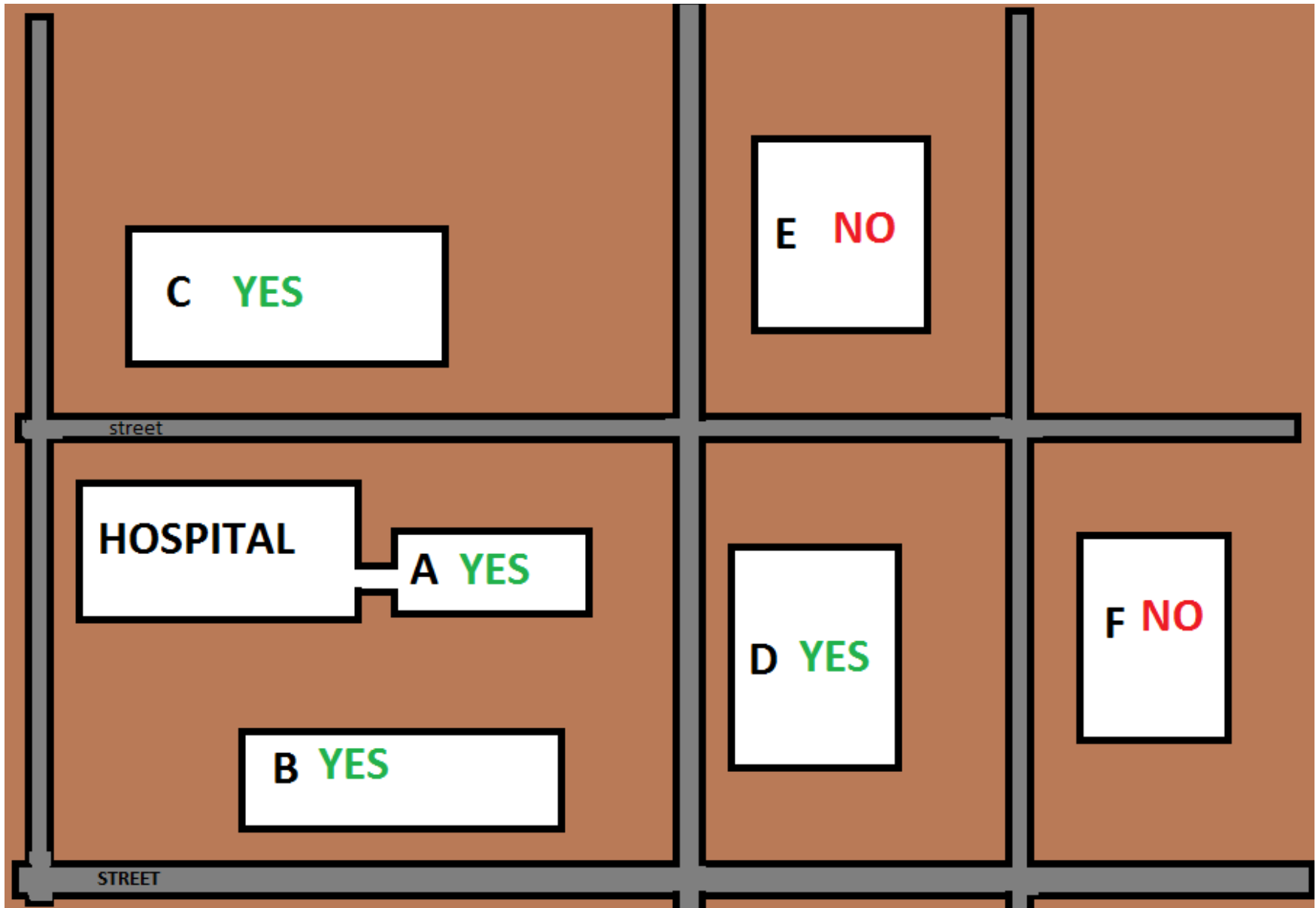
Hospital premises:

- (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?

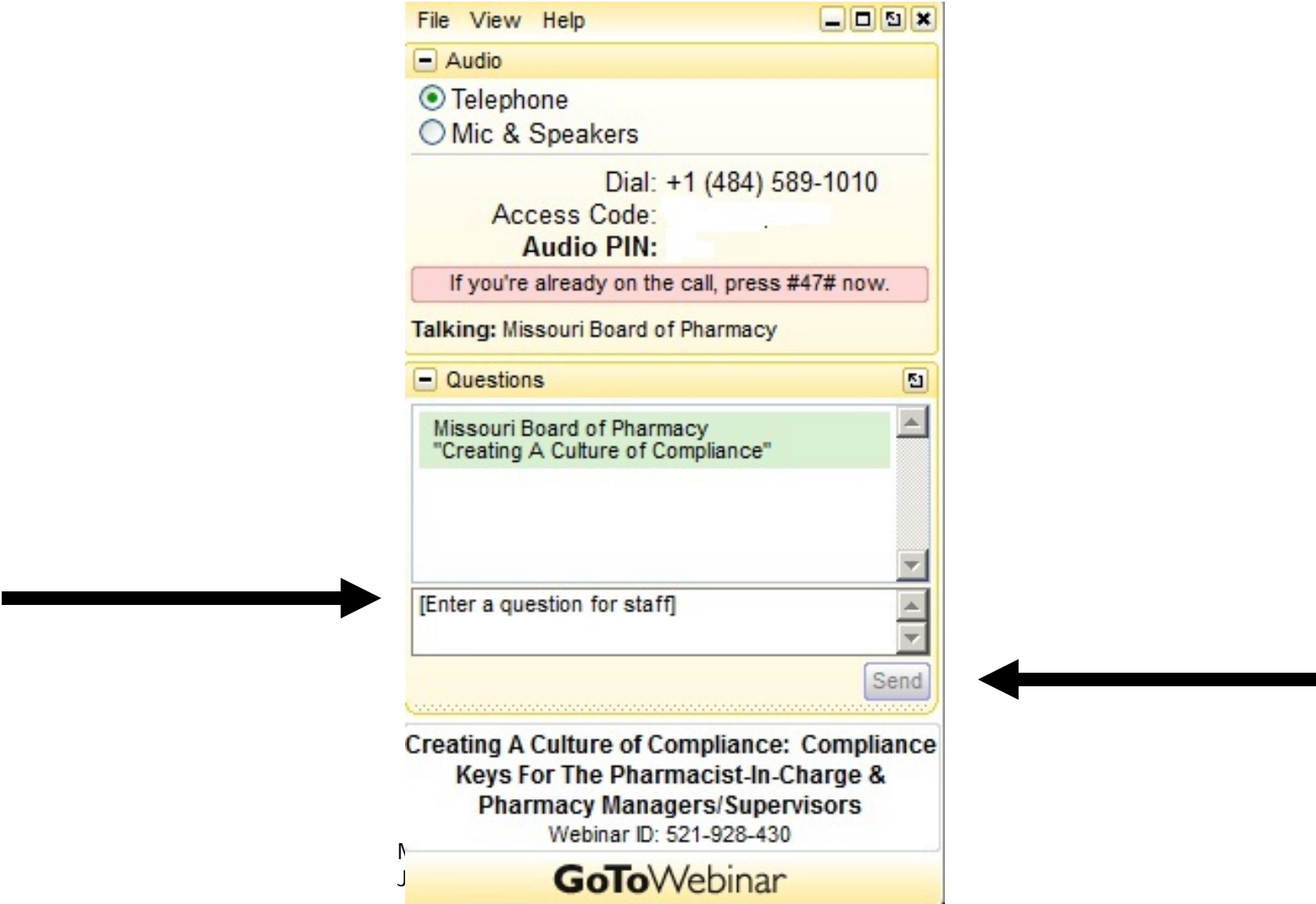
# Questions-Rules

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



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# Contact Information

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