

Past, Present, and Potential Future Directions for Rules and Regulations Related to Health System Pharmacy Practice in Missouri

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Disclosure

The speakers have no conflicts of interest to disclose in relation to this program.

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Program Objectives

- Review the historical context for the current rules and regulations related to health system pharmacy practice in Missouri.
- Discuss current rules and regulations and potential future directions that impact health system pharmacy practice in Missouri.
- Express questions, concerns and ideas regarding modified rules/regulations that impact health system pharmacy practice in Missouri.

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Program Outline

- History of hospital pharmacy regulation
- Supreme Court decision
- Issues with today's regulatory structure
- Board's strategy
- Board update
- MSHP updates
- Question and Answer/Discussion

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Regulatory History

- Prior to 1984
- 1984: Board promulgates regulations
 - 4 CSR 220-2.070 *Hospital Pharmacy Services*
 - 4 CSR 220-2.080 *Electronic Data Processing*
 - 4 CSR 220-2.090 *Pharmacist-in-Charge*

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Supreme Court Decision

- 1987 Missouri Hospital Association, et al v. Department of Consumer Affairs, Regulation, and Licensing
 - No Board authority over an inpatient pharmacy
 - Board cannot require permit for inpatient
 - Voided *Hospital Pharmacy Services* regulation
 - Other Board rules do not apply to inpatient
 - Department of Health (now DHSS) has authority over an inpatient pharmacy

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Supreme Court Decision

Board's authority in hospitals:

"The Board's power extends only to those hospital pharmacies which act in the traditional "drug store/pharmacy" role, for example, when physician prescriptions are filled for out-patients, members of the public, or hospital employees."

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Court Decision Effects

- Dual agency roles
 - DHSS regulates inpatient activity
 - BOP regulates outpatient activity
- Inpatient vs. outpatient

Not defined by:

- Court decision
- State statute
- BOP regulation
- DHSS regulation

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Court Decision Effects

- BOP continues authority over:
 - Individual licenses (pharmacist, intern, technician)
 - Intern-training facilities
 - Drug distributors

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Regulatory History

- Post court decision
 - DHSS promulgates hospital pharmacy regulation
 - BOP and DHSS have interactions on some issues
 - BOP regulates hospital outpatient dispensing with same regulations as other pharmacy classes

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Today

- Practice of pharmacy
 - Evolving faster than dual regulatory structure
 - No longer just dispensing
 - Clinical practice advancing
 - Hospital systems expanding outside of DHSS premises
- Confusion and uncertainty

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Scenario 1

Inpatient pharmacy compounds drug to be administered in medical building on hospital campus. Does BOP have jurisdiction?

- A. Yes
- B. No

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Inpatient vs. Outpatient

- Board inspection interpretation:
 - A drug administered to a patient within the DHSS licensed hospital premises is considered inpatient
 - Regardless of patient billing status
- DHSS premises
 - Building(s) licensed by DHSS as hospital

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Current Issues

- Offsite pharmacy practice
 - Chemotherapy infusion centers
 - Clinical services
- Distribution beyond premises
 - Hospitals, clinics, surgery centers, infusion centers
 - Drug distributor 5% rule
 - Controlled substances
- Compounding for other hospitals in same system

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Current Issues

- Dispensing/labeling issues
 - Multi-dose containers on discharge
 - Transfer of patients
 - Quantities that can be provided without pharmacy involvement
 - Automatic dispensing systems
- Records
 - Hospital orders vs. prescriptions
 - Electronic recordkeeping systems

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Scenario 2

Pharmacist adjusts inpatient's warfarin dose based on hospital protocol. Does the pharmacist need a *Certificate of Medication Therapeutic Plan Authority* from the Board of Pharmacy?

- A. Yes
- B. No

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Current Issues

- Medication therapy services
- Pharmacist administration
- Use of technicians
 - Medication reconciliation
 - Tech check tech
 - Remote supervision

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Current Issues

- Technology
 - Remote order verification
 - Remote product verification
- Drug shortages
 - Receipt of drugs from unlicensed entities

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Board Strategy

- Working group
- Regulation changes
- Statutory changes

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Hospital Working Group

- Meeting Facilitator: Kevin Kinkade, R.Ph.
- Eighteen group members
 - MSHP
 - MHA
 - MPA
 - DHSS
 - DMH
 - Large hospitals
 - Small hospitals
 - BOP

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Hospital Working Group

- Pharmacists from
 - Cooper County Memorial Hospital-*Boonville*
 - CoxHealth-*Springfield*
 - University of Missouri Health Care-*Columbia*
 - Mercy Hospital-*Springfield*
 - Missouri Baptist Hospital-*Sullivan*
 - Heartland Regional Medical Center-*St. Joseph*
 - Barnes-Jewish Hospital-*St. Louis*
 - Golden Valley Memorial Hospital-*Clinton*
 - St. Mary's Health Center-*Jefferson City*

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Hospital Working Group

- Topics
 - BOP/DHSS jurisdiction
 - Inpatient/outpatient definitions
 - DHSS premises
 - Clinical practice
 - MTS
 - Pharmacist administration
 - Automation/technology
 - Central fill
 - Remote verification

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Hospital Working Group

- Topics
 - Compounding
 - Sterile
 - Non-sterile
 - Compounding for other hospitals
 - Compounding for office use
 - Dispensing/labeling
 - Discharge, transfer, emergency department
 - Multi-dose containers
 - Recordkeeping

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Hospital Working Group

- Topics
 - Drug distribution
 - Outside of premises
 - Between hospitals
 - Distributor licensure requirement
 - Technicians
 - Scope
 - Competency

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Hospital Working Group

- Topics
 - Board hospital member position
 - Current statute: *“provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility or an intermediate care facility”*
 - Permanent hospital advisory committee
 - Similar to drug distributor committee
 - DHSS pharmacist consultant position

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Board Strategy

- Possible regulation temporary fix
 - Relief for offsite practice locations
 - Orders
 - Labeling
 - Recordkeeping
 - Access to pharmacy
 - Emergency rule
- Statute revisions
 - Requires legislation

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Board Update

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Board Update

- Statute and regulation changes
- Proposed legislation and regulations
- Board initiatives
- Future activity

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2012 Statute Changes

Drug Distribution

- 338.315
 - Distribution from out of state pharmacies without MO license
- 338.333
 - Exemption from licensure for emergency or to alleviate supply shortage

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2012 Statute Changes

- School nurses 167.635
 - Asthma rescue medications
 - Prescription in school district's name
 - Similar to 167.630 epinephrine auto syringes
- Controlled substances
 - 195.060 / 195.080
 - Out of state prescribers
 - Quantity limits
 - 334.747 Physician assistant BNDD numbers

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Recent Regulation Changes

- Medication Therapy Services
 - 20 CSR 2220-6.060 *General Provisions*
 - 20 CSR 2220-6.070 *Certificate of Medication Therapeutic Plan Authority*
 - 20 CSR 2220-6.080 *Medication Therapy Services By Protocol*
- More information—Board Website
 - Compliance Guide, Q&A
 - Webinar

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Recent Regulation Changes

- 20 CSR 2220-2.013
 - *Prescription Delivery Requirements*
 - Identifies where prescription may be delivered
 - Written policies and procedures
- 20 CSR 2220-2.145
 - *Minimum Standards for Multi-Med Dispensing*
 - Allows return and repackaging for therapy change on same patient

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Recent Regulation Changes

- 20 CSR 2220-2.675
 - *Standards of Operation/Licensure for Class L Veterinary Pharmacies*
- 20 CSR 2220-4.010
 - *General Fees*
 - Pharmacist renewal decreased by \$25

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2013 Legislative Proposal

- Emergency refills
- New permit classes
 - Class M: Specialty (bleeding disorder)
 - Class N: Automated dispensing system (health care facility)
 - Class O: Automated dispensing system (ambulatory care)
 - Class P: Practitioner office/clinic
- Authority to test drugs

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Proposed Regulations

- 20 CSR 2220-6.100 *Pharmacy Standards for Dispensing Blood Clotting Products*
 - Effective 5/30/13
- Complete revision to pharmacist and intern licensing regulations
 - Six regulation rescissions
 - Ten new regulations

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Proposed Regulations

- 20 CSR 2220-2.083 *Electronic Record-Keeping Systems*
 - Electronic images instead of hard copy
 - Three other rule revisions
- 20 CSR 2220-2.950 *Automated Filling Systems*
 - Pharmacist verification requirements
- Implement 338.315/338.333 revisions
 - Distribution by out of state pharmacy
 - Emergency and drug supply shortage

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Board Initiatives

- “Compliance is Key” initiative ended



- All compliance resource still available online
 - Found under [Publications/Resources](#) link
 - 2013 *Missouri Pharmacy Practice Guide*
 - *Pharmacy Self Assessment Guide*
 - Webinars, FAQ’s, other guidance documents

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Board Initiative

- 2013 *MoSafeRx* Patient Safety Initiative



- Board’s website
 - Numerous links and information
 - Webinar

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Future Board Activity

- USP 797
 - Consideration on officially adopting
- Compounding for office use
- Technician training and competency
- Prescription drug take back regulation
 - DEA National Take-back Day
 - Saturday April 28, 2013

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MSHP Updates

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MSHP Strategic Priorities

- Increase MSHP participation with the Board of Pharmacy
- Work with MPA to achieve common goals
- Engage with MHA to further hospital pharmacy practice

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Board of Pharmacy Activities

- Letter to the Board addressing hospital concerns – Spring 2012
- Participating in Hospital Working Group
 - Supports working with the Board for hospital oversight

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Coalition Updates

- Continue to have a representative to discuss statewide issues
- Opportunity to work with MPA towards common goals
 - Discharge information to community locations

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Other Legislative Items

- Prescription Tracking program
 - Currently in committee
- Biosimilars
 - ASHP writing a position statement

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Question and Answer Discussion

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Post Test

1. The 1987 Supreme Court decision ruled that the Board of Pharmacy has authority over hospital inpatient pharmacies.
 - A. True
 - B. False

2. After the 1987 Supreme Court decision the Board of Pharmacy continued to have authority over which of the following individuals working in a hospital inpatient pharmacy?
 - A. Pharmacists
 - B. Intern Pharmacists
 - C. Technicians
 - D. All of the above.

3. A pharmacist preparing chemotherapy drugs outside of the DHSS licensed premises of the hospital would be required to have a pharmacy permit from the Board of Pharmacy.
 - A. True
 - B. False

4. Current topics being discussed by the Board of Pharmacy's hospital working group include all of the following except:
 - A. Use of technicians
 - B. Emergency refill dispensing
 - C. Definition of "outpatient"
 - D. Dispensing of multi-dose container upon patient discharge

5. The role of Board of Pharmacy's hospital working group is to advise the Board on matters related to the practice of pharmacy within hospital systems?
 - A. True
 - B. False

6. The Board of Pharmacy's 2013 MoSafeRx initiative relates to
 - A. Promoting compliance
 - B. Prescription drug take back programs
 - C. Promoting patient safety
 - D. Controlled substance dispensing

7. In addition to epinephrine pens, pharmacies may dispense the following drug using a prescription in the name of a school district?
 - A. Tetanus vaccine
 - B. Malathion lotion
 - C. Diphenhydramine injection

D. Asthma rescue medication

8. 2013 Board of Pharmacy legislation proposals include:

- A. Emergency refill dispensing
- B. New pharmacy permit classes
- C. Authority to test drugs
- D. All of the above