

The New & Proposed Changes to the Hospital Licensing Rules

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Conflict of Interests

- Daniel Good is an employee of Cardinal Health
- Bert McClary is a consultant with the Missouri Department of Health
- No conflicts of interest have been identified.



MSHP Public Policy Committee Activity

- Medication Therapy Management Rules
- The Technician Initiative
- Missouri Pharmacy Coalition
- Missouri Pharmacy Care Network
- Pharmacy Legislative Day
- Definition of Legend Drug related to Investigational Drugs
- Access to Medications during drug shortages
- Hospital Pharmacy Licensing Rules



Department of Health and Senior Services (DHSS)

Includes :

- Bureau of Health Services Regulation
- Bureau of Narcotics and Dangerous Drugs
- Bureau of Emergency Medical Services
- Bureau of Home Health and Hospice
- Section for Long Term Care



Regulation of Hospital Pharmacy

- DHSS
- CMS
- Board of Pharmacy




Board of Pharmacy Authority

- Statutory authority
- Limited inpatient authority



Hospital Licensing Regulations

- 19 CSR 30-20 Hospitals
- <http://www.sos.mo.gov/adrules/csr/current/19csr/19csr.asp#19-30>
Select Chapter 20 Hospitals
- 19 CSR 30-20.100
Pharmacy Services and Medication Management
- Last major revision 1995




Regulation Review Process

- Overall review committee
- Pharmacy/Medication rule review committee
- Department management review
- Board of Health review
- Proposed rule to Secretary of State




Regulation Review Process (cont)

- Publish proposed rule in Missouri Register
- Public comment period
- Department/Board of Health response and final rule
- Response and final rule to Secretary of State
- Publish final rule in Missouri Register




Reasons for Suggesting Changes

- Inquiries from hospitals for interpretations
- Suggestions from hospitals for changes
- Consistent with CMS regulations and interpretive guidelines
- Consideration of other standards of practice
– ASHP, ISMP, TJC, other
- BOP emphasis of limited authority



General Categories in Current Rule


(1) - (5)	Organization and Management
(6) - (14)	Medication Storage, Acquisition and Recordkeeping
(15) - (18)	Medication Preparation
(19) - (29)	Medication Distribution
(30) - (32)	Other Pharmacist Professional Responsibilities
(33) - (40)	Medication Orders and Administering



Possible Changes

Section (33) **Medication order authority**

- Independent statutory authority
- Individual physician practice agreements
- Hospital based agreements



Possible Changes

Section (34) Medication protocols

- Oversight by P&T
- General content & requirements
- Protocols that require a medication order
- Protocols that do not require a medication order
- Proposed BOP rule



How would you vote?

- Medications may be ordered by Respiratory Therapists:
 - a. Independently according to their scope of practice
 - b. According to protocols approved by pharmacy and health system medical staff
 - c. Should not be allowed



How would you vote?

- Pharmacists may order medications:
 - a. Independently according to their scope of practice
 - b. According to protocols approved by pharmacy and health system medical staff
 - c. Should not be allowed



Possible Changes

Section (37) Administering Medications

- Training and restrictions for non-licensed persons
- Selection of dose by another person



How would you vote?

- Administration of medications in procedural areas (cath lab, GI lab, radiology) can be performed by technologists:
 - a. Independently according to their scope of practice
 - b. Under direct supervision of physician
 - c. According to protocols approved by pharmacy and health system medical staff
 - d. Should not be allowed



Possible Changes

Section (2) Technicians

- Minimum standard for education and training
- Consider certification requirement
- Levels of activity based on technical skills required and potential for patient harm



How would you vote?

- Pharmacy technicians working in hospitals:
 - a. Should be required to be certified by PTCB upon hire
 - b. Should be required to be certified by PTCB within ___ months of hire date
 - c. Should be certified based on their responsibilities within a hospital (i.e. Compounding of sterile products)
 - d. Should not be required to be certified



Possible Changes

Sections (10) and (11) **Controlled substances**

- Inventory frequency
- Security



Possible Changes

Section (17) **Sterile compounding**

- Recognize USP <797>
- Risk levels
- Who may prepare
- Equipment, environment, etc



Possible Changes

New Section (X) Hazardous Medications

- Require policies & procedures
- Identification, storing, equipment, preparation, labeling, transport, cleanup, disposal



Possible Changes

Section (19) **Patient medication profile**

- Who may make entries
- Pharmacist review requirements
- Patient data requirements
- Remote review



Possible Changes

Section (22) **Distribution systems**


- Traditional manual
- Automated technologies



Possible Changes

Section (29) Take-home medications when pharmacist unavailable


- Automated dispensing systems for take-home medications



Possible Changes

New Section (X) Distribution to locations outside the hospital


- Hospital premises definition
- Same hospital license at second location
- BOP drug distributor



Possible Changes

New Section (X) Medication disposal


- Identify categories
- Identify waste streams for each
- Recognize DNR, EPA, NRC requirements



Possible Changes

Section (35) Medication orders


- Signature
- Content
- Verbal orders
- Communication of information



Possible Changes

New Section (X) Medication safety

- Requirements for medication safety program



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ICHP/MSHP 2011 Spring Meeting

Missouri Law – The New and Proposed Changes to the Hospital Pharmacy Rules

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Post Test Questions:

1. Which Missouri state agency oversees hospital pharmacy regulations?
 - A. Board of Pharmacy
 - B. BNDD
 - C. Department of Health and Senior Services
 - D. Bureau of Home Health and Hospital Licensing

2. What is the final step in promulgating hospital medication management rule language?
 - A. Approval by Board of Pharmacy
 - B. Publishing final rule in Missouri Register by Secretary of State
 - C. Responding to public comments
 - D. Approval by Board of Health

3. Technician education and training requirements for advanced activities should be based on:
 - A. High school diploma or GED
 - B. PTCB exam score
 - C. ASHP accredited training program certificate
 - D. Technical skills required and potential for patient harm

4. Pharmacists in Missouri currently have statutory authority to provide medication therapy services according to:
 - A. Centers for Medicare and Medicaid Services
 - B. Department of Health and Senior Services
 - C. Board of Pharmacy
 - D. Bureau of Health Services Regulation

5. The following practitioners have independent statutory authority to prescribe in Missouri:
 - A. Nurses, physician assistants and physicians
 - B. Physicians, dentists and podiatrists
 - C. Pharmacists, physicians and veterinarians
 - D. Physician assistants, nurses and respiratory therapists

6. New sections for the Pharmacy Services and Medication Management rule suggested by the Bureau of Health Services Regulation include:
 - A. Hazardous medications and a medication safety program
 - B. Sterile compounded products and hazardous medications
 - C. Disposal of medications and pharmacy auxiliary personnel
 - D. ED dispensing and unit dose systems