Joint Commission and CMS Update - 2012

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- The ASHP Research and Education Foundation requires that all faculty disclose any relevant financial relationships. These relationships should not be assumed to have an adverse impact on faculty presentations.
- No relevant financial relationships exist.
- Patricia C. Kienle is an employee of Cardinal Health.

Objectives
- List recent changes in CMS Hospital Conditions of Participation related to medications
- Identify the top Joint Commission non-compliant medication issues
- Cite recent changes in JC standards
- Discuss the requirements for medication integrity
- State the required elements of a medication order
- List policy requirements for timing of medication administration

Who Makes the Rules?

Regulatory Agencies
- Federal and state agencies that affect licensing and/or operation of a hospital
- Centers for Medicare and Medicaid Services (CMS)
- State Department of Health
- State Board of Pharmacy

More Regulatory Agencies
- Drug Enforcement Administration
- Food and Drug Administration
- Occupational Health and Safety Administration
- Nuclear Regulatory Commission
- …
Accreditation Organizations

- The Joint Commission
- American Osteopathic Association
  - Healthcare Facilities Accreditation Program
- DNV Healthcare
  - National Integrated Accreditation for Healthcare Organizations

Standards of Practice

- United States Pharmacopeia
- ASHP – Best Practices

CMS Conditions of Participation

- Basis for regulatory requirements and accreditation standards
- Pharmaceutical Services, and
  - Medical Records
  - Nursing Services
  - Nuclear Medicine

Parts of the CoPs

- Condition of Participation
  - Tag number
  - Interpretive Guidelines
  - Survey Procedures

§482.25 Pharmaceutical Services

- Meet needs of the patients
- Drug storage
- Responsible pharmacist
- Adequate number of personnel
- Accurate records of scheduled drugs
- Controlled and distribution meets applicable standards of practice, law, and regulation
- Compounding only under pharmacist supervision and consistent with laws

Policies 02-02-P, 02-05-P, 22-01-P, RX15-03, RX15-04

... Pharmaceutical Services ...

- All drugs and biologicals kept in a secure area, and locked when appropriate
- Controlled substances locked within a secure area
- Only authorized personnel have access to locked areas
- Outdated, mislabeled, or otherwise unusable drugs and biologicals not available for patient use

... Pharmaceutical Services

- Only authorized personnel remove drugs and biologicals from a storage area
- Automatic stop order policy
- Errors, ADRs, and incompatibilities reported to attending physician and hospital committee
- Abuses and losses of controlled substances reported to DOP and CEO
- Drug information available to professional staff
- Formulary system


Other Medication-Related CoPs

- Medical Record Services
  - §482.24(c)(1)
  - Orders
  - Protocols
- Nursing Services
  - §482.23(c)
  - Administration of medications
- Nuclear Medicine Services
  - §482.53(b)
  - In-house preparation of radio pharmaceuticals

Policies 10-02-H, 13-01-H, RX08-02

Recent CoP Changes

- Orders and protocols
  - Required elements
  - Authentication of multi-page orders
- Timing of medication administration
  - Change in the “30 minute” rule

Policies 10-02-H, 13-09-H

TJC Top Non-Compliant Issues

<table>
<thead>
<tr>
<th>Rank</th>
<th>Standard</th>
<th>Non-Compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RC.01.01.01 The hospital maintains complete and accurate medical records for each patient</td>
<td>65%</td>
</tr>
<tr>
<td>6</td>
<td>MM.03.01.01 The hospital safely stores medications</td>
<td>33%</td>
</tr>
<tr>
<td>10</td>
<td>MM.04.01.01 Medication orders are clear and accurate</td>
<td>28%</td>
</tr>
</tbody>
</table>

2011 Joint Commission Changes

- MM.02.01.01 Selecting Medications
- Prelabelling of syringes

Policies 08-02-H, 11-05-P, 11-09-H

Key Areas for Compliance

- Selection
  - Pediatric issues
- Storage
  - Integrity of meds
- Orders
  - Protocols
- Dispensing
  - Labeling syringes
- Administration
  - Timing

Select → Store → Order
Monitor ← Administer ← Dispense
Selection of Medications

- MM.02.01.01: The hospital selects and procures medications
- EP 2: The hospital develops criteria for selecting medications, which, at a minimum, include the following:
  - ... Population(s) served (for example, pediatrics, geriatrics) ...
  - Also added pediatric focus to two PC standards
  - Pain management and risks for falls

Policies 08-02-H, 08-03-H, 22-20-P

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Storage of Medications

- Security
- Safety
- Integrity of medications

Policies 09-01-P, 09-02-H, 13-03-H, RX15-05

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Security – Controlled Substances

- Lock all controlled substances
- Include C-V
- Include procedural areas and clinics
- No unauthorized access

Policies 09-01-P, RX15-05

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Security – All Medications

- Lock all meds unless hospital policy permits otherwise
- Define who is authorized to access medications
- Automated and manual systems must meet same standards
- Flush solutions

Policies 09-01-P, RX15-05

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Are these secure?

Policies 09-01-P

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Integrity of Medications

- In date
- Correct temperature
  - Use manufacturer’s information

Policies 09-01-P, 09-02-H, 09-03-P, 09-04-H
Use Manufacturer’s Storage Info

- CMS CoP §482.41 – Temperature Control
  - The hospital must ensure that pharmaceuticals are stored properly and in accordance with manufacturer’s recommendations…
- MM.03.01.01 – Safe Storage
  - EP 1 - The hospital stores medications according to the manufacturers’ recommendations or, in the absence of such recommendations, according to a pharmacist’s instructions
- Problematic drugs

Manufacturers’ Information

- Storage temperature
  - Room temperature
  - Moving refrigerated items to room temperature
  - Moving room temperature items to warmers

Orders – Required Elements

- Name of patient
- Age and weight of patient, when applicable
- Date and time of the order
- Drug name
- Exact strength or concentration, when applicable
- Dose, frequency, and route
- Quantity and/or duration, when applicable
- Specific instructions for use, when applicable
- Name of prescriber

Orders

- Must be unambiguous
  - Legible
  - Complete
  - Dated and timed
- Applies on any type of order
  - Handwritten
  - Preprinted
  - Electronic
- Protocols
  - Detailed information in CoP

Policies 09-01-P, 09-02-H, 09-04-H, 09-06-H

Policies 09-02-H, 09-04-H, 09-06-H

Policies 09-01-P, 09-02-H, 09-04-H, 09-06-H

Policies 10-01-H, 10-02-H, 10-09-H

Policies 10-01-H, 10-02-H, 10-09-H
Is this a clear, unambiguous order?

Medication Protocols
- Develop with prescriber(s)
- Consistency of practice
- Unique name of protocol
- Avoid therapeutic duplication if possible
- Orders require objective parameters
  - Taper
  - Titrate
  - Therapeutic duplication
- CMS views this as a medical decision, not one of convenience or non-LIP judgement

Policies 10-01-H, 10-02-H, 10-09-H

Prelabeling Syringes
- NPSG.03.04.01: Labeling medications
  - Deals with labeling during procedures
- MM.05.01.09: Medications are labeled
- Communication between The Joint Commission and the American Society of Anesthesiologists
  - The Joint Commission no longer prohibits pre-labeling syringes


Is this safe?

Policy 11-09-H

Medication Administration Timing
- Change in the “30 minute rule”
- November 2011 change in CMS Interpretive Guidelines and Survey Procedures
- Change advocated by ASHP, ISMP, and Joint Commission
- Hospital needs to define policy and medications that are time-critical and must be given within 30 minutes of the scheduled time

Policies 13-01-H, 13-09-H

Policy Elements
- Establish standard times
- Develop written policy that includes
  - Meds not eligible for standard dosing times
  - Meds eligible for standard dosing times
  - Time-critical scheduled medications
  - Action for medications outside of scheduled dosing times and windows

Policies 13-01-H, 13-09-H
Not Eligible for Standard Times

- Hospital policy needs to define
- Suggestions
  - Stats
  - First time or loading doses
  - One-time doses
  - Time sequenced doses
  - Investigational drugs
  - PRNs

Meds Eligible for Standard Times

- Hospital policy needs to define
- Suggestions
  - Meds ordered on a repeated cycle of frequency
  - Policy needs to specify those medications that are time-critical

<table>
<thead>
<tr>
<th>Antibiotics</th>
<th>Pain medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticoagulants</td>
<td>Orders for a specific time</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>Orders that must be separated</td>
</tr>
<tr>
<td>Immunosuppressive agents</td>
<td>Meds ordered more frequently than every 4 hours</td>
</tr>
</tbody>
</table>

CMS Requirements for Timing

<table>
<thead>
<tr>
<th>Type of Order</th>
<th>Maximum Allowance Outside of Scheduled Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time-critical</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Scheduled more frequently than daily but no more frequently than every 4 hours</td>
<td>1 hour</td>
</tr>
<tr>
<td>Scheduled for daily, weekly, or monthly</td>
<td>2 hours</td>
</tr>
</tbody>
</table>

First and Subsequent Dose Timing

<table>
<thead>
<tr>
<th>Standard Medication Administration Times for Scheduled Medications</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type of Order</th>
<th>Maximum Allowance Outside of Scheduled Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Critical Management</td>
<td>45 minutes</td>
</tr>
<tr>
<td>3.2 Critical Management</td>
<td>1 hour</td>
</tr>
<tr>
<td>3.3 Critical Management</td>
<td>2 hours</td>
</tr>
<tr>
<td>3.4 Critical Management</td>
<td>3 hours</td>
</tr>
<tr>
<td>3.5 Critical Management</td>
<td>4 hours</td>
</tr>
</tbody>
</table>

Infection Prevention

- Multiple dose vials
  - Use single use vials as much as possible
  - Use for one patient only
  - Preservatives are not effective against viruses and fungi
- Never use infusion supplies for more than one patient
  - Syringes, needles, and cannulas are used for a single patient for a single procedure

Safe Injection Practices

Policies 13-01-H, 13-09-H

Policies 37, 336

Policies 13-01-H, 13-09-H

Policies 38

Policies 39

Policies 40

Policies 41

Policies 42


While the use of aseptic technique when preparing and administering injectable medications is applicable to all healthcare settings, including pharmacy areas, these FAQs are not intended to reflect the standards and recommended practices for handling medication vials and related products in pharmacy settings—these should be determined in accordance with the state boards of pharmacy, the United States Pharmacopeia (USP), the Drug Enforcement Agency (DEA), and the Food and Drug Administration (FDA).

Exemption for Pharmacy

- While the use of aseptic technique when preparing and administering injectable medications is applicable to all healthcare settings, including pharmacy areas, these FAQs are not intended to reflect the standards and recommended practices for handling medication vials and related products in pharmacy settings—these should be determined in accordance with the state boards of pharmacy, the United States Pharmacopeia (USP), the Drug Enforcement Agency (DEA), and the Food and Drug Administration (FDA).

National Guidelines

- CDC: Safe Injection Practices to Prevent Transmission of Infections to Patients
- CDC: Prevention Checklist for Outpatient Settings – Minimum Expectations for Safe Care
- APIC: Safe Injection, Infusion, and Medication Vial Practices in Health Care
- USP: Compounding Sterile Preparations

Action Steps

- Read the medication sections of the CMS Conditions of Participation
- Know your state regulations
  - State board of pharmacy
  - State department of health
- Review hospital policies and medical staff bylaws and rules & regulations
- Ensure your policies, procedures, and practices are current

Resources

- Comprehensive Accreditation Manual for Hospitals, Joint Commission
- Joint Commission Perspectives
- Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide, 8th edition, ASHP
- USP <797>, June 2008 update

CHS Medication Management Compliance

Jerry Reed, M.S., R.Ph., FASCP
Director of Pharmacy Operations
Community Health Systems
Objectives

- Summarize CHS 2011 TJ C Medication Management survey results
- Review additional non-compliant issues in CHS facilities related to Medication Management

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2011 Medication Management Survey Findings

- MM.03.01.01 EP 2, 3, 6-8
- MM.04.01.01 EP 1, 6-8, 10, 13
- MM.05.01.01 EP 1 - 3, 8
- MM.05.01.09 EP 1, 4, 10
- MM.05.01.11 EP 4
- MM.05.01.13 EP 1
- MM.08.01.01 EP 5
- NPSG 03.04.01 EP 1-3, 6

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2011 Medication Management Survey Findings

Top MM Standards Scored Non-Compliant by Year

<table>
<thead>
<tr>
<th>Standard Subject</th>
<th>TJC-2009</th>
<th>TJC-2010</th>
<th>TJC-2011</th>
<th>CHS-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM.03.01.01 Storage</td>
<td>33%</td>
<td>34%</td>
<td>34%</td>
<td>22%</td>
</tr>
<tr>
<td>MM.04.01.01 Orders</td>
<td>30%</td>
<td>28%</td>
<td>25%</td>
<td>36%</td>
</tr>
<tr>
<td>MM.05.01.01 EPK Review</td>
<td>13%</td>
<td>16%</td>
<td>14%</td>
<td>26%</td>
</tr>
<tr>
<td>MM.01.04.03 HRHA Medications</td>
<td>7%</td>
<td>6%</td>
<td>7%</td>
<td>0%</td>
</tr>
<tr>
<td>MM.05.01.07 Prep</td>
<td>0%</td>
<td>3%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>MM.05.01.09 Labeling</td>
<td>0%</td>
<td>3%</td>
<td>3%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Policies 09-02-H, RX15-05

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MM.03 Storage

- Unauthorized personnel with access to drugs
- Crash carts storage
- Terminated employees remain in ADCs
- Medications prepared without a BUD
- Unsecured carts and kits with meds
- Proper temperature storage


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MM.03 Storage

- Policies addressing safe storage

Policies 09-01-P, 09-02-H, 09-03-P, RX15-05,

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MM.03 Storage

- Unsecured drugs
- Unlocked med room
- Unsecured prescription pads

Policies 09-02-H, RX15-10
MM.03 Storage

- MDV expiration dates

Policy 21-06-H

MM.03 Storage

- Disposal of CS waste without a witness
- Expired medications
- Patient’s own medications

Policies 09-01-P, 09-02-H, 09-03-P, 13-03-H

MM.04 Medication Orders

- Policy for LASA drugs
- Telephone and verbal orders
- Medication protocols or order sets
- Resume orders
- Therapeutic duplications
- Titration orders
- No evidence of order review by pharmacist

Policies 08-12-H, 10-02-H, 10-03-H, 10-05-H

MM.05 Preparing and Dispensing

- Order review by a pharmacist
- Multiple drugs ordered for pain
- Room number used as a patient identifier on drug storage bins


MM.05 Preparing and Dispensing – Patient Care Areas

- Labeling


MM.05 Preparing and Dispensing – Procedural Areas

Policies 11-09-H, 22-03-P
MM.05 Preparing and Dispensing – Procedural Areas

MM.08 Medication Management System Evaluation

- Collect and analyze data
- Identify data over time to identify risk points
- Review current literature for new technologies and best practices
- Medication Reconciliation processes
- Identify opportunities as priorities
- Evaluate changes to confirm improvements
- Annual report

Additional Medication Management Opportunities

- Drugs in Gift Shops
- Chemicals stored in patient care areas
- Thermometer calibration
- Pill crushers and tablet splitters
- Compounding products
- Drug Recalls
- USP Chapter <797> Survey Results
- USP Chapter <795> Standards
- EPA RCRA-compliant Pharmaceutical Waste Program
- Implementation of new policies

Additional Medication Management Opportunities

- Pill Crushers and Tablet Splitters

- Compounding Products

Drug Recall System

- MM.04.01.17
- Recall terms
  - Class I, II, or III recall
  - FDA Enforcement Report
  - Market withdrawal
  - Mandatory recall
  - Medical device safety alert
  - Phantom recall
  - Voluntary recall
  - Withdrawal
- RASMAS (Risk and Safety Management Alert System)
  - Web-based notification service
  - Pilot sites

USP Chapter <797> Survey

- 23 Questions
- 2,944 total responses (128 facilities)
- 330 non-compliant responses (11.2%)
USP Chapter <797> Survey – The Good News

- ACDs are recalibrated at least once daily. (100%)
- All CSPs (non-immediate use) are prepared in ISO 5. (99%)
- Spare glovebox arm sleeves on hand. (99%)
- Competencies for high-risk compounding. (99%)
- All CSPs prepared by a technician are checked by a second person. (98%)
- Hoods are certified every 6 months. (98%)
- Glovebox sleeves are changed at least once annually. (97%)
- Hoods are never turned off unless being serviced. (96%)
- Anterooms adjacent to cleanrooms are ISO 7. (95%)

USP Chapter <797> Survey – The Other News

- Gloved fingertip sampling (59%)
- Surface sampling for viable organisms (62%)
- CSP quality control program developed and includes a sampling plan (75%)
- Temperature, humidity, and pressure differential monitoring (75%)
- Nursing personnel complete competencies for “Immediate Use” compounding (80%)
- Pre-filters are changed monthly (80%)

USP Chapter <795> Standards

- Non-sterile compounding
- Update official in May, 2012
- 3 Types
  - Simple – reconstitution or adding a component to a product as instructed by the manufacturer
  - Moderate – calculations required or compounding when stability references are not available
  - Complex – specialized training or equipment necessary
- Competencies
- Dedicated compounding area
- Recipes and master formulation approval, including Beyond-Use-Dating
- Record keeping

Pharmaceutical Waste – Statistics for U.S. Hospitals

- Compliance Rates
- Hazardous Drugs Identified

Pharmaceutical Waste

New Policies Implemented

- Acute Care CS policies
- Ambulatory Surgery Centers
- Physician Practice and Clinic Policies
- Long Term Care
Implementation of Electronic Clinical Surveillance Initiative – Sentri7 & Quantifi

Trent Beach, Pharm.D., M.B.A., M.H.A., FASHP
Director of Clinical Pharmacy Services
Community Health System

Sentri7 & Quantifi

Sentri7
- Supports real-time clinical decisions
- Gathers and displays patient specific information based on predefined criteria
- Optimizes time to identify assessment and intervention opportunities

Quantifi
- Supports intervention documentation
- Integrates with Sentri7 allowing partial auto-population of data.
- Provides information needed to demonstrate productivity

Sentri7 & Quantifi

Rules
- Logic designed to identify specific patients
- A standardized set of rules will be provided
- Customized rules may be created to meet facility needs

Intervention Types
- Will be centrally coordinated for standardization across the system
- Associated with hard and soft dollar savings where appropriate

Sentri7 & Quantifi

Implementation Timeline

Pilots (4)
January 23 – April 6

Remediation Wave 1 & 2 (7)
February 6 – April 13
February 13 – April 27

Phase I (40)
May 7 – September 7

Phase II (40)
September 17 – January 11, 2013

Phase III (40)
January 28 – May 31

Sentri7 & Quantifi

Training & Go Live Support

User Training
- Live Online Training from P1S Team
- Comprehensive Training Manual
- Video Tutorial

Go Live Support
- Assigned P1S Online Support

Ongoing Support
- PRN Training from P1S Support Team
- CHS Super Users

Sentri7 & Quantifi

Results

Strong performance anticipated/expected

- Usage will be gathered and analyzed
- Feedback will be provided
- Results will be reported through divisional leadership
- Our success depends on all of us
Update on Current CHS Initiatives and Strategies

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Chief Pharmacy Executive
Community Health System