Program Objectives for Pharmacists & Technicians: Upon completion of this program, participants should be able to:
1. List the four most problematic medication related standards and National Patient Safety Goals in terms of non-compliance by organizations surveyed in hospitals in 2010 and the most common reasons why each was scored non-compliant.
2. Cite the new interpretation of the standard requirements related to beyond-use dating of multi-dose vials and the CDC guidelines related to Safe Injection Practices as it pertains to pharmacy practice.
3. Describe the changes and new requirements for the medication-related standards and National Patient Safety Goals for 2011, including medication reconciliation.

Speaker: Darryl Rich, PharmD, MBA, FASHP, is a surveyor for The Joint Commission in the hospital, home care, and ambulatory accreditation programs. In addition, he works for the Standards Interpretation Group serving as an internal resource for The Joint Commission related to pharmacy and medication management. He previously served as Associate Director for Surveyor Management and Development at The Joint Commission for 11 years. Dr. Rich has been with The Joint Commission since January 1993.

Prior to coming to The Joint Commission, Dr. Rich was National Director of Pharmacy Services for Critical Care America, Inc., a national home infusion company. Previously, he served as Director of Pharmacy Services at Boston University Medical Center and Clinical Assistant Professor of Pharmacy at Northeastern University.

Dr. Rich received his Doctor of Pharmacy degree from the University of California at San Francisco and a Master’s in Business Administration in Health Care Management from Bryant University in Rhode Island.

Speaker Disclosure: Darryl Rich reports he is a speaker’s bureau member and receives a salary from The Joint Commission. The speaker has indicated that off-label use of medications will not be discussed during this presentation.
Learning Objectives

- Upon completion of this program pharmacists (or pharmacy technicians) will be able to:
  - List the four most problematic medication-related standards and National Patient Safety Goals in terms of non-compliance by organizations surveyed in hospitals in 2010 and the most common reasons why each was scored non-compliant.
  - Cite the new interpretation of the standard requirements related to beyond-use dating of multi-dose vials and the CDC guidelines related to Safe Injection Practices as it pertains to pharmacy practice.
  - Describe the changes and new requirements for the medication-related standards and National Patient Safety Goals for 2011, including medication reconciliation.

Pre-Assessment Questions

- Having inconsistent range orders continues is the top medication management standard non-compliance issue in 2010.
- One of the top issues in radiology related to medications is the storage and use of a 500 ml multi-dose vial of radiographic contrast in the radiology department despite the manufacturer’s package insert describing this vial as a Pharmacy Bulk Package for use only in a laminar flow hood.
- Unapproved abbreviations remains the top medication-related National Patient Safety Goal scored on surveys in 2010.
- The use of the date opened on a multi-dose vial with a policy that states that the vial expires 28 days from opening, is not an acceptable alternative to labeling the product with the last date that the product is to be used.
- The top non-compliance issue related to the new NPSG for anticoagulation management relates to the implementation of an approved written protocol for the initiation and maintenance of anticoagulation therapy in all patients receiving warfarin, heparin and LMW heparin.

Question

What was the most common reason for noncompliance in the MM standards for 2009-10?

A. Medication carts not located in secure area, locked room, or under constant surveillance.
B. Not clarifying unclear, incomplete or illegible orders.
C. Incorrect beyond use dating of multi-dose vials.
D. Lack of pharmacist review of medication orders for variation from hospital-approved indications for use.
Top Medication Standards Scored Non-Compliant in 2010*

<table>
<thead>
<tr>
<th>Standard</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM.03.01.01 Medication Storage</td>
<td>31%</td>
</tr>
<tr>
<td>MM.04.01.01 Medication Orders</td>
<td>30%</td>
</tr>
<tr>
<td>NPSG 03.04.01 Labeling in Procedures</td>
<td>27%</td>
</tr>
<tr>
<td>MM.05.01.01 Pharmacist Review</td>
<td>15%</td>
</tr>
<tr>
<td>MM.05.01.09 Medication Labeling</td>
<td>7%</td>
</tr>
<tr>
<td>MM.01.01.03 High Alert Medications</td>
<td>7%</td>
</tr>
<tr>
<td>MM.05.01.07 Medication Preparation</td>
<td>6%</td>
</tr>
<tr>
<td>MM.08.01.01 Med System Evaluation</td>
<td>6%</td>
</tr>
</tbody>
</table>

*Based on surveys Jan-Jun 2010

Medication Security

- Medicare Conditions of Participation – Federal Register 11/27/06, effective 1/28/07
  - All drugs and biologicals be kept in a secure area, and locked when appropriate. (EP 3)
  - Schedules II, III, IV, and V drugs must be kept locked within a secure area. (EP 3)
  - Only authorized personnel as defined in policy may have access to locked areas. (EP 6)

Medication Security 

- L&D and ICUs considered secure if entry and exit are limited to appropriate staff, patients & visitors
- OR Suite is secure only if active and staffed
- Due to mobility, mobile carts must be in a locked room or under constant surveillance.
- Medications at bedside only if self-administered
- Janitors, maintenance and other staff may have access ONLY if in organization policy

Medication Security Issues

- Carts not located in secure area of floor or locked room
  - Not within observation of nurses
  - In corridors with public access
- Medications lying around on counters
- Unlicensed personnel have access to medications, without being authorized to do so in hospital policy.
  - Housekeeping/maintenance staff in closed OR
- Locked areas, not locked.

Problem Areas

- OR’s
- C-Section Room
- Procedural Areas
- Radiology, Nuclear Medicine
- Clinics
- Inpatient Units
Medication Storage Issues

- EP 1: Not storing drugs per manufacturer’s recommendation (28%)
- EP 8: Expired drugs not removed (18%)
- EP 7*: Stored medications not labeled (8%)
  - No expiration date, no/wrong beyond use date.
- EP 5: No policy on handling of drugs while in possession of staff. (7%)
- EP 9: No justification for conc. electrolytes in pt. care area. (3%)
  * = direct impact EP

Beyond Use Date

- See Perspectives June 2010
- The Joint Commission requires organizations to re-label multi-dose vials with a revised expiration date (beyond use date) once these vials are opened or punctured.
  - Cannot be labeled with date opened – see FAQ.
- The Joint Commission requires a revised expiration date of 28 days from the date of opening or puncture except....

Beyond Use Date

- Exceptions to 28 day dating:
  - If manufacturer specifies otherwise in package insert or other documentation.
  - If the manufacturer’s original expiration date is shorter than the revised expiration date, then the shorter date must be used.
  - If sterility is questioned or compromised the multi-dose vial should be discarded.
  - Does not apply to vaccines.
  - Note: Does apply to allergy (allergen) MDV.

Safe Injection Practices

- IC.01.05.01, EP 1 – Must incorporate CDC Safe Injection Guidelines in P&P.
- IC.02.01.01, EP 2 – Must follow CDC Safe Injection Guidelines in practice.
  - For guidelines see:
  - Joint Commission Perspectives. October 2010

Safe Injection Practices

- Examples from CDC Guidelines:
  - “Do not administer medications from single-dose vials or ampules to multiple patients”
  - “Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients”

BoosterPaks

- First one: MM.03.01.01
  - Standard & implementation expectations
  - Frequently asked questions, definitions of key terms, and additional information on specific topics
  - Supporting documentation, CMS tags, evidence, development process, field testing, value, historical info, additional references and links.
    - Available on hospital’s intranet site.
Medication Ordering

Top non-compliance issue for MM.04.01.01:
- EP 13* – Implementation of policy (50%)
  - Failure to clarify unclear, illegible and incomplete orders (top reason).
  - Titration orders without initial rate or clear parameters for titration,
  - Range orders without parameters for when to give what dose in range.
  - Other

Other EP's scored:
- EP 1: No written policy on specific types of medication orders that are acceptable for use. (7%)
- EP 6: Use of verbal and telephone medication orders not minimized. (7%)
- EP 7: Preprinted order sheets not reviewed and updated in timeframe (13%)
- EP 8*: Summary (blanket) resume orders not prohibited in policy (7%)

Other Major Radiology Issues

- No medication/solution labeling when needed
- No “beyond-use” dating of opened multi-dose vials.
- Dispensing oral contrast (legend drug) to outpatients not in adherence to standards.
- Lack of aseptic technique in medication prep
- Patient identification just at entry to area – not prior to medication administration.
- Non-standardized concentrations of heparin
- Use of pharmacy bulk vials
- No medication reconciliation in outpatients
  Also Nuclear Medicine!

Question

For MM.05.01.01 – Pharmacist Review of Medication Orders, which of the following was the top non-compliance issue scored:

A. Not defining in policy role of LIP during contrast administration with protocol-based approach.
B. No pharmacist review of non-contrast meds in radiology and nuclear medicine and other areas.
C. No pharmacist review for variations from hospital approved indications for use.
D. Failure of pharmacist to review orders with therapeutic duplication.
Key SII MM Changes for 2009

- MM.05.01.11, EP 3* – The hospital dispenses medications within timeframes it defines to meet patient needs
- MM.05.01.01, EP 10* – Medication orders reviewed for:
  - Variations from hospital-approved indications for use.

* = direct impact EP

Expectations

- Drugs should be added to formulary for specific indications for use (MM.02.01.01, EP 2)
- Annual review of formulary drugs should address indications for use (MM.02.01.01, EP 3)
- A diagnosis, condition, or indication for use must exists for each medication (MM.04.01.01, EP 9)
- Pharmacists must have access to this information when reviewing orders (MM.01.01.01, EP 1)

Expectations

- Pharmacist must review orders for variations from hospital-approved indications for use (MM.05.01.01, EP 10)
  - Determined on survey by interview with RPh.
- Variations are clarified with the individual prescriber before dispensing (MM.05.01.01, EP 11)
  - Actions taken are at discretion of pharmacist and/or pharmacy's clinical intervention process.
  - Data should be returned for review at P&T.
    - FAQ available soon.

Top MM Standards Scored Non-Compliant in 2010

- MM.05.01.09 – Med Labeling (7%)
  - EP 1* Drugs not labeled (37%)
    - When not immediately administered.
      - Immediately administered (glossary): no intervening steps between prep and adm.
  - EP 3* No medication strength on label (16%)
  - EP 4* No expiration date on label (12%)
  - EP 7* No patient name when required (8%)

* = direct impact EP

Top MM Standards Scored Non-Compliant in 2010

- MM.01.01.03 – High Alert and Hazardous Meds (7%)
  - EP 3* Not following policy for high alert and hazardous medications (32%)
  - EP 2 No processes for high alert and hazardous medications (27%)
  - EP 1 No list of high alert and hazardous medications (21%)
    - Conc. Electrolytes in patient care areas not identified as high-alert.

* = direct impact EP

New CMS requirements

- MM.01.01.03 – High Alert Meds
  - New CMS elements of performance:
    - EP 5: Reports abuses and losses of controlled substances to the pharmacy director and, as appropriate, to the CEO. (6%)
Top MM Standards Scored Non-Compliant in 2010

- MM.05.01.07 – Drug Preparation (6%)
  - EP 1*: Not all sterile meds prepared by pharmacy (62%)
    - Outpatient clinics, procedure areas.
    - Elastomeric Infusion pumps ("pain balls") for post-op pain
  - EP 2*: When prepared outside of pharmacy (nursing units), not done in a functionally separate area that is clean, uncluttered, & dedicated solely for IV preparation (18%)
    - ED, ICU, & non-pharmacy areas

CMS Pharmacy Related EP's

- MM.05.01.07 Medication Preparation
  - EP 5*: Medications are prepared and administered in accordance with the orders of a licensed independent practitioner responsible for the patient’s care and law and regulation (18%)

* = direct impact EP

A Word about Broselow Tapes

- 2007a tape – glucogon dosing error
  - If error or old tape not fixed/addressed
    - scored at IM.03.01.01, EP 1
  - Competencies in using tape not identified
    - scored at HR.01.06.01, EP 1

Question

Which are the top compliance issue with the anticoagulation management goal NPSG 03.05.01?

A. Lack of a written medical staff protocol for initiation and maintenance of warfarin therapy
B. Not followed by retail pharmacies owned and operated by the hospital.
C. Lack of physician/patient education.
D. Lack of periodic evaluation process (measures)
E. No baseline INR’s prior to starting therapy.

Note: Overall non-compliance 2.5%
**Elements of Performance**

- EP 2* Uses written approved protocols for initiation and maintenance of therapy (50%)
  - Does not address prescribing (initiation & maintenance) for all anticoagulants
  - Guidelines not distributed/available to prescribers
- EP 8 Evaluates anticoagulation safety practices and takes action, & measure effectiveness (25%)
  - No measures for evaluation.
- EP 3* Assesses INR prior to start/adjust warfarin – must be documented (19%)

* = direct impact EP

**Revision for 2011**

- 6. A written policy addresses baseline and ongoing laboratory tests that are required for heparin and low-molecular weight heparin therapies. *Anticoagulants.*
  - Policy can say "no tests" for LMW heparin.

**Medication Reconciliation**

- NPSG 03.06.01 - July 2011.
  - EP 1: Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital or is seen in an outpatient setting. This information is documented in a list or other format that is useful to those who manage medications.
    - Scheduled and PRN medications
    - Good faith effort to obtain accurate list.
    - Must be part of the medical record and in standardized format (IM, RC).

**Medication Reconciliation**

- EP 2: Define the types of medication information to be collected in non-24-hour settings and different patient circumstances.
  - ED, Primary Care, OP Radiology, Amb Surg, Diagnostic
- EP 3: Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital to identify & resolve discrepancies.
  - Discrepancies include omissions, duplications, contraindications, unclear information, and changes.
  - Done by qualified individual, competency-assessed.

**Medication Reconciliation**

- EP 4: Provide the patient with written information on the medications the patient should be taking when discharged from the hospital or at the end of an outpatient encounter.
  - When the only additional medications prescribed are for a short duration, the medication information the hospital provides may include only those medications.
- EP 5: Explain the importance of managing medication information to the patient when discharged from the hospital or at the end of an outpatient encounter.

**How The Medicare Conditions of Participation are Surveyed**

- Surveyors survey the JC standards.
  - COP are built into the standards (elements of performance) – cross-walked.
    "For hospitals that use Joint Commission accreditation for deemed status purposes:
  - COP are considered law and regulation
  - Use CMS interpretative guidelines in interpreting standards.
Parting Suggestions

- Periodic review of all areas where medications are used.
- Be sure to address hot patient safety issues in media.
- Work with your Joint Commission Coordinator
- Don't panic – focus on big issues not the obscure.

New Solution Resources

- BoosterPaks.
  - Available to Organizations on their Joint Commission intranet site
- Center for Transforming Health Care
  - www.centerfortransforminghealthcare.com
- Leading Practices Database
  - Recently Available to Organizations on their Joint Commission intranet site.

Questions

For questions about the interpretation of Joint Commission standards, organizations (or the public) can submit their questions by either:
- Calling the Standards Interpretation Unit at 630-792-5900
- Submitting the question in writing by using the following on-line form:
  http://www.jointcommission.org/Standards/OnlineQuestionForm/

Post-Assessment Questions

- Having inconsistent range orders continues is the top medication management standard non-compliance issue in 2010. (False)
- One of the top issues in radiology related to medications is the storage and use of a 500 ml multi-dose vial of radiographic contrast in the radiology department despite the manufacturer’s package insert describing this vial as a Pharmacy Bulk Package for use only in a laminar flow hood. (True)
- Unapproved abbreviations remains the top medication-related National Patient Safety Goal scored on surveys in 2010 (False)

- The use of the date opened on a multi-dose vial with a policy that states that the vial expires 28 days from opening, is not an acceptable alternative to labeling the product with the last date that the product is to be used. (True)
- The top non-compliance issue related to the new NPSG for anticoagulation management relates to the implementation of an approved written protocol for the initiation and maintenance of anticoagulation therapy in all patients receiving warfarin, heparin and LMW heparin (True)