CSSI: Compliance Strategies for Survival and Influence

Activity Overview

Pharmacy leaders must ensure compliance with many different regulations, such as TJC, DEA, CMS, BOP, OSHA…and that's just the start. Come away from this session with monitoring, record-keeping, and risk-management strategies to manage these complex requirements, as well as methods for helping the C-suite understand and value the importance of these functions.

Learning Objectives

After participating in this application-based educational activity, participants should be able to

- Differentiate between regulatory and accreditation agencies and their impact on the health care enterprise.
- Identify Centers for Medicare and Medicaid Services (CMS) Conditions of Participation that impact the operation of the pharmacy enterprise.
- Identify medication-related elements that can impact publically-reported data.
- Develop a medication-diversion prevention plan involving all areas within the health care enterprise.
- Design a readiness plan to ensure that medication-related data requested during an audit could be produced in a credible and timely manner.
Accreditation

- Organization must be certified by the Centers for Medicare and Medicaid Services (CMS) to participate in the federal Medicare program.
- CMS confers “deemed status” on a health care organization when that organization is in compliance with CMS standards and has been accredited by certain organizations.
Accreditation Agencies

- Hospital
  - The Joint Commission (TJC)
  - Healthcare Facilities Accreditation Program (HFAP) of the American Osteopathic Association (AOA)
  - National Integrated Accreditation for Healthcare Organizations (NIAHO) program of Det Norske Veritas (DNV)

- ASC
  - The Accreditation Association for Ambulatory Health Care (AAAHC)
  - TJC

Office of Civil Rights

- Civil Rights
  - Helps protect from discrimination in health care

- Health Information Privacy Rights
  - Protects the privacy of your health information
  - Enforces the confidentiality provision of the Patient Safety Act and Rule

Office of Inspector General (OIG)

- Mission to protect the integrity of Department of Health & Human Services (HHS) programs and program beneficiaries
- Fight waste, fraud, and abuse in Medicare, Medicaid, and other HHS programs
- Audits, investigations, and evaluations
- Legal situation
OIG Penalties

- Official Medicare Program Termination
- Monetary Penalties
- Quality Sanctions
- Immediate Jeopardy
- Serious Substantial
- Gross & Flagrant
- Hospitals and Physicians

Quality Improvement Organization (QIO)

- Monitor the appropriateness, effectiveness, and quality of care provided to Medicare beneficiaries
- Protection of consumers
- Private contractor extensions of CMS
- Emergency Medical Treatment and Active Labor Act (EMTALA)
- Statement of Work

State Department of Health & Licensure

- Licensure Regulations & State Laws
- Board of Medical Licensure
- Clandestine Laboratory Investigators Association's (CLIA) Lab/Pathology
Publically-Reported Measures

- Hospital Quality Alliance (HQA)
- National Quality Forum (NQF)
- Leapfrog

Drug Enforcement Agency (DEA)

- DEA Office of Diversion Control
  - Enforcing the Federal Laws & Regulations relating to Schedules II to V
  - Onsite Audits and Inspections of Controlled Substances
- DEA Inspection What to Do
  - Provide a conference room & privacy
  - Identify your contact person
  - Provide all DEA required records

Records for DEA Audit

- Biennial Inventory Report
- Inventory Records
- Executed DEA Forms 222 & Invoice
- Theft and Loss Reports (DEA Form 106)
- Destruction Report (DEA Form 41)
- Due Diligence Policies
CMS

- Medicare Program Termination Recommendation to OIG
- Public Notice
- Medicare Payment Stopped
- Contract:
  - State Survey Agency of Enforcement
  - QIO (Statement of Work)
  - OIG

FOUNDATIONAL OPERATIONS CERTIFICATION AND STANDARDS COMPLIANCE

- THE JOINT COMMISSION (TJC)
- ACCREDITATION ASSOCIATION FOR AMBULATORY HEALTHCARE (AAHC)
- CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) AND EXTERNAL AGENCIES – FEDERAL AND STATE SURVEY AGENCIES (SSA)
- QUALITY “COLLABORATIVES”
  - BUSINESS COALITIONS
  - LEAPFROG
  - QUALITY IMPROVEMENT ORGANIZATIONS
- ENFORCEMENT
  - LOCAL, STATE AND FEDERAL

Enlarged on page 13
Who Directs Us?

- What organization drives the establishment of policies, procedures, and practices in hospitals and related organizations?
  - Federal agencies
  - State laws and regulations
  - Accrediting organizations

CMS Conditions of Participation

- CMS Hospital Conditions of Participation (CoP)

Accrediting Organization Standards

- TJC
  - CoPs + professional organization best practice documents + practitioner groups
- AOA’s HFAP
  - CoPs + NQF-Endorsed Set of 34 Safe Practices
- DNV’s NIAHO
  - CoPs + International Organization for Standardization (ISO) Quality Standards
Medication Standards

- TJC – 134 Medication Management (MM) Elements of Performance
  - 47 are Direct Impact requirements
- HFAP – 105 Standard Elements
- NIAHO – 57 Standard Requirements
- 17 Pharmaceutical Services Standards

Medication Use System

Planning ➔ Select ➔ Store ➔ Order ➔ Dispense ➔ Evaluation

Monitor ➔ Administer

CoP Pharmaceutical Services

- General issues
- Storage
- Dispensing
- Other issues
  - Medical Staff (orders)
  - Nursing Services (administration)
  - Nuclear Medicine (radiopharmaceutical)
  - Human Resources (competency)
Message to Enterprise

- Traditional services
- Clinical services
- Expanded roles

CoPs - General

- Pharmacy, with a director, guided by medical staff-approved policies and procedures
- Pharmacist to coordinate activity
- Adequate number of personnel
- Abuses and losses of controlled substances reported to director and CEO
- Drug information available

CoPs - Selection

- Formulary of quality pharmaceuticals at reasonable cost
CoPs - Storage

- Storage administered with acceptable professional practices
- All drugs and biologicals secure; locked when appropriate
- Controlled substances locked within a secure area
- Access only to authorized personnel
- Outdated drugs not available for patients

CoPs - Orders

- Automatic stop order policy

CoPs - Dispensing

- Accurate controlled substances records
- Distribution in accordance with federal and state laws and applicable standards of practice
- All compounding, packaging, and dispensing of drugs and biologicals under supervision of pharmacist and consistent with federal and state laws
- Removal only by authorized personnel in absence of pharmacist
CoPs - Administration

CoPs - Monitoring

- Drug administration errors, adverse drug reactions (ADR), and incompatibilities are reported to the attending physician and to the hospital-wide quality assurance (QA) program.

CoP Components

- Condition of Participation
- Standard
- Interpretive Guideline
- Survey Procedures
Focus on the Enterprise Needs

- C-suite angst
  - Surveys
  - Public opinions
- Geometric progression of issues with Enterprise
- You: keep things in control

Hot Buttons

- Controlled substance integrity
- Fiscal accountability
- Medication safety
- Patient safety and public expectations

Keeping the Enterprise Safe

- Developing a diversion prevention plan
- Preparing for an audit
- Responding to publically-reported data
SUGGESTED READINGS


4. Joint Commission Resources. Everything you ever wanted to know about performance measurement at the joint commission but were afraid to ask. The Source. 2012; 10:12-6.

CASE STUDY
DEVELOPING A DIVERSION PREVENTION PLAN

Diversion prevention software has just been installed throughout the facility. During the first month it is noted by the Director of Pharmacy that there is a significantly higher use of oxycodone and hydrocodone in the ED. In addition the nurse manager has been reviewing the medication administered reconciliation report and has noticed an increase in number of medications not scanned prior to administration. This report flags medications that have been removed from the automated dispensing cabinet but not scanned prior during the BCMA process. The interdisciplinary diversion team gets together at their bi-monthly meeting and starts to notice a trend of data in the ED. Upon further review it is found that medications have been removed on several patients post discharge. After an intensive review, five staff are called into HR for questioning. Four staff refuse drug testing and quit immediately. One staff agrees to the drug testing and then confesses that the group has been diverting medications from the ADC on patients that have just been discharged, but are still listed in the system.

CORE ELEMENTS TO INCLUDE IN YOUR PLAN

- Human Resources
- Reporting (local, state, national) DEA 106, state licensure board, local police
- Investigation
- Closed loop system (how to identify gaps)
- Multidisciplinary approach to diversion prevention

METRICS

- Benchmarking reportable events
- Using data for quality assurance (diversion software and internal reports)
- Others?
CASE STUDY

PREPARING FOR AN AUDIT

The local Recovery Audit Contractor (RAC) for your region has flagged a case for payment review. Payment has been stopped on a 24 hour ops patient. The patient was admitted with a history of metastatic breast cancer with a chief complaint of uncontrolled pain. During the admission the patient received pamidronate sodium 90 mg IV administered as a 2 hour infusion. It was decided that the patient would be transferred to hospice and the patient was discharged within 23 hours. The hospital is fully live on barcode medication administration. Billing occurs upon administration. The pamidronate was built into the drug dictionary based on mg dosing. The case is sent to you for review. The CMS requirements: Pamidronate Disodium (J2430) represents 30 mg per unit. Providers are billing for units representing the milligrams, not the correct unit of one (1) unit for every 30 mg administered. At this time, Medical Necessity will be excluded from this review. But you have found that the patient was treated for bone metastases secondary to breast cancer. You find that the pamidronate is not set up appropriately in the pharmacy dictionary and that CMS has been billed for 90 units instead of 3 units. The pharmacy dictionary is updated to reflect billing based on NDC unit, for each 30 mg vial that was administered the patient would be billed 1 unit.

ASSURING THAT YOUR DATA IS ACCESSIBLE AND ACCURATE

- Developing checklist for audits (CMS, FDA, DEA, etc.)
- Steps to assuring pharmacy drugs are set up appropriately in the health information management system
- Process for change based on regulatory changes (recalls) or billing changes (addition of new CMS approved issues for review)

METRICS

- Number of RACs reviewed in a year
- Others?
The updated HCAHPS scores have been posted on www.HospitalCompre.hhs.gov. The executive team has called a meeting of hospital leadership. The hospital is performing below the national average and lower than the hospitals in the geographical area. The CEO wants each director to write a one-page Strategic Plan on the role of their department in improving patient experience.

WHAT PHARMACY SERVICES ARE INCLUDED

- Pain Management
- Medication Information
- Medication Side Effects

HOW CAN YOU DEMONSTRATE PHARMACY SERVICES VALUE TO THE C-SUITE

- Metrics besides HCAHPS scores
- Defining the value of pharmacist role in improving publically and privately reported metrics
- Others?
# Joint Commission Medication-Related Direct Impact Elements of Performance

Based on 2012 Standards – Update 2

<table>
<thead>
<tr>
<th>Standard</th>
<th>EP</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>IM.02.02.01</td>
<td>3</td>
<td><strong>Prohibited abbreviations</strong></td>
</tr>
<tr>
<td>NPSG.01.01.01</td>
<td></td>
<td><strong>Patient identifiers</strong></td>
</tr>
<tr>
<td>NPSG.03.04.01</td>
<td></td>
<td><strong>Labeling</strong> – procedures</td>
</tr>
<tr>
<td>PC.03.01.01</td>
<td></td>
<td><strong>Sedation</strong></td>
</tr>
<tr>
<td>PC.01.02.07</td>
<td></td>
<td><strong>Pain</strong> control</td>
</tr>
<tr>
<td>PC.02.01.03</td>
<td></td>
<td><strong>Verbal order</strong> – read back</td>
</tr>
<tr>
<td>MM.01.01.03</td>
<td></td>
<td><strong>High alert</strong> and <strong>hazardous meds</strong></td>
</tr>
<tr>
<td>MM.01.02.01</td>
<td>2</td>
<td>Implement policy</td>
</tr>
<tr>
<td>MM.02.01.01</td>
<td>6</td>
<td><strong>Select and Procure</strong></td>
</tr>
<tr>
<td>MM.03.01.01</td>
<td></td>
<td><strong>Storage</strong></td>
</tr>
<tr>
<td>MM.03.01.03</td>
<td>7</td>
<td>Label with contents</td>
</tr>
<tr>
<td>MM.03.01.03</td>
<td>9</td>
<td>Concentrated electrolytes in patient care areas</td>
</tr>
<tr>
<td>MM.03.01.03</td>
<td>10</td>
<td>RTU in patient care areas</td>
</tr>
<tr>
<td>MM.03.01.05</td>
<td>2</td>
<td><strong>Emergency Medications</strong></td>
</tr>
<tr>
<td>MM.04.01.01</td>
<td>8</td>
<td>Prohibit blanket orders</td>
</tr>
<tr>
<td>MM.05.01.01</td>
<td></td>
<td><strong>Pharmacist review</strong></td>
</tr>
<tr>
<td>MM.05.01.07</td>
<td>1</td>
<td>Pharmacist compounds all CSPs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clean, uncluttered, functionally separate area</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Inspect for particulates, discoloration, loss of integrity</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>ISO5 in pharmacy if not used within 24 hours</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Prepared and administered per order of LIP</td>
</tr>
<tr>
<td></td>
<td>In-house preparation of radiopharmaceuticals</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MM.05.01.09**  
**Labeling**

<table>
<thead>
<tr>
<th></th>
<th>Labeled when not immediately administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Med name, strength and amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Exp date when not used with 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Exp time when exp occurs in less than 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>CSPs and TPNs include date prepared and diluents</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>For multiple patients: Patient name</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>For multiple patients: Directions and cautionary instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>By another person: Directions and cautionary instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td></td>
</tr>
</tbody>
</table>

**MM.05.01.11**  
**Dispensing**

<table>
<thead>
<tr>
<th></th>
<th>Within defined time frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

**MM.05.01.13**  
**When pharmacy closed**

<table>
<thead>
<tr>
<th></th>
<th>Implements processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

**MM.06.01.01**  
**Administration of meds**

<table>
<thead>
<tr>
<th></th>
<th>Only authorized LIPs and clinical staff administer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Med matches order</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Visual inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Med not expired</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>No contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Proper time, dose and route</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Unresolved concerns discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Patient informed re clinically significant ADR with new med</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

**MM.06.01.03**  
**Self-administered meds**

<table>
<thead>
<tr>
<th></th>
<th>Patient is competent</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

**MM.06.01.05**  
**Investigational meds**

<table>
<thead>
<tr>
<th></th>
<th>Implements processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

**MM.07.01.03**  
**ADEs, ADRs, Medication Errors**

<table>
<thead>
<tr>
<th></th>
<th>Implements processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Errors, ADRs and incompatibilities reported to LIP and QA/PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>