Pharmacy Audits – How Can the Pharmacy Staff Get Involved?

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Learning Objectives
1. Review main Joint Commission (TJC) and 340B Medication Management standards and requirements
2. Outline the preparatory process and identify strategies for successful TJC and 340B audits
3. Discuss potential roles pharmacy technicians can play in the preparation for an audit
4. Recognize how the “lessons learned” from the audit can be used to improve compliance with the set standards

Things Fall Apart

• Second Law of Thermodynamics - Increased Entropy
  The Second Law of Thermodynamics is commonly known as the Law of Increased Entropy. While quantity remains the same (First Law), the quality of matter/energy deteriorates gradually over time.

  As usable energy is irretrievably lost, disorganization, randomness and chaos increases

Chaos Increases

So it’s not our fault!

• It's a universal law of physics that left alone, processes, and organization fall apart.
• TJC prep should not be just before the survey, but should be a continual state of readiness- so that patient care is provided at a high level.
• Safe and efficient systems
• Happy pharmacy staff (or at least less stressed).

What it feels like when TJC arrives- ZOMBIE APOCALYPSE
The Joint Commission Audits

- Tom Wheeler- PharmD, BCPS, CPHIMS
- Corporate Director of Pharmacy Rush University Medical Center- Chicago

Gap Analysis

- Current practice- top deficiencies are technical not clinical- lending them selves to pharmacy tech leadership.
- Best Practice- continual state of readiness. Think aircraft carrier.
- Education Need- what is the area to focus on, what documentation is necessary.
- Learning objective- how to get to full and continual compliance.

Med Errors- How Can We Provide Safe and Efficient Care?

- Our drugs can Cure and Kill.
- Medication Management standards- are termed MM.
- 8 different areas.
- TJC Standards are in place to provide a framework for an effective and SAFE medication management system.

What are the Areas?

- Planning
- Selection and procurement
- Storage
- Ordering
- Preparing and dispensing
- Administration
- Monitoring
- Evaluation

Needs Assessment

- What do you need to know?
- Readiness is not just for pencil pushing coffee drinking directors and managers.
- Some of the section is higher level planning.
- Most involve front line pharmacy technicians and pharmacists.
- An engaged staff is a compliant and safe department.

What is TJC

A. New frozen yogurt franchise
B. Non binding Quality Agency
C. Government Agency
D. Accrediting organization —for Medicare and Medicaid
The Joint Commission

- Established in 1951.
- Focus on safety and quality.
- Deemed status accrediting agency—Medicare doesn’t have inspectors.
- Located in Oakbrook.
- Once was the only game in town, now DNV, etc.

If TJC walked into 4 of your med rooms

A. Unlikely to find unsecured meds
B. Possible to find unsecured meds
C. Likely to find unsecured meds
D. We are in trouble

What are the standards?

- MM – The goal is to provide a framework for an effective and safe medication management system
- Very little clinical requirements
- 8 different sections

MM I-VIII

- Planning
- Selection and Procurement
- Storage
- Ordering and Transcribing
- Preparing and Dispensing
- Administration
- Monitoring
- Evaluation

What does TJC State Should Be Done?

- Reduce variation, errors and misuse.
- Evidence Based Practice.
- Manage CRITICAL processes to promote safe medication management.
- Standardize, standardize, standardize.
- Monitoring the medication management process for efficiency, quality and safety.

Medication Management- Top NonCompliant Standards/NPSGs for Hospitals (Jan-Dec, 2015)

<table>
<thead>
<tr>
<th>Standard/NPSG</th>
<th>% Non-compliant</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM.03.01.01 Storage and Security of Meds</td>
<td>34%</td>
</tr>
<tr>
<td>MM.04.01.01 Medication Orders</td>
<td>30%</td>
</tr>
<tr>
<td>MM.05.01.01 Medication Order Review</td>
<td>15%</td>
</tr>
<tr>
<td>NPSG.03.04.01 Labeling in OR/procedures</td>
<td>10%</td>
</tr>
<tr>
<td>MM.05.01.07 Preparing medications</td>
<td>6%</td>
</tr>
<tr>
<td>NPSG.03.06.01 Reconciling Medications</td>
<td>4%</td>
</tr>
<tr>
<td>MM.05.01.09 Labeling medications</td>
<td>4%</td>
</tr>
<tr>
<td>MM.01.02.01 Look alike sound alike Med</td>
<td>3%</td>
</tr>
<tr>
<td>MM.01.01.03 High alert /Hazardous Meds</td>
<td>3%</td>
</tr>
</tbody>
</table>
### MM.01.01.03
**High Alert and Hazardous Drugs**

- And yes- you will probably get a raise if you go to you director and quote the standard number.
- This standard – high-alert and hazardous meds.
- If you think you know of a better way to minimize admin errors for these SPEAK UP.

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### High alert Medications MM 01.01.03

- We define them –yes- you and I
- Do you know what your site strategy is
- Audience participation- name some
- Does everyone at your site know? How is this communicated?

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### The Hospital Selects and Procures Medications MM 02.01.01

- Standardize and limits concentrations-why?
- Need a formulary- and it needs to be "readily available"
- Non formulary meds
- Drug Shortages
- substitutions

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### What are your High alert and Hazardous meds

**Audience Participation**

- Each site must have a list?

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### SALAD

**Look Alike Sound Alike Medication Strategies (MM.01.02.01)**

- Consider multiple concentrations of the same medication.
- Have you defined policy on ordering LASAs?
- Recommendation: Address display of LASAs with TALLman lettering, use of brands or indications; address storage via restrictions preparation, labeling.

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### MM.03.01.01 Medication Storage and Security ☆ Problematic EPs

EP 2: medications are stored according to manufacture’s recommendations –
EP 3: all medications and biologicals are stored in secure areas to prevent diversion and locked when necessary, in accordance with law and regulation – Failure to address diversion –
EP 6: the hospital prevents unauthorized individuals from obtaining medications in accordance with law and regulation –
EP 7: all products are labeled with contents, expiration date (Bulk Packaging-Imaging) –
EP 8: removes expired, damaged, and/or contaminated meds/stores separately
MM 03.01.03
- The hospital safely manages emergency medications.
- Readily available.
- Whenever possible in unit –dose age-specific.
- When used- they are replaced promptly.

MM 04.01.01
- Medication orders are clear and accurate.

MM 05.01.01
- A Pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital

MM 05.01.07
- The hospital safely prepares medications.
- This is entirely within the scope of the day to day activities.
- Do you speak up if there is a problem?
- Do you speak up if a coworker isn’t measuring up?

Remember NECC
- New England Compounding
- 800 sickened, 52 died
- Pharmacy preparation errors happen
- Complex processes, different staff, ever changing formulas and drugs

MM 05.01.09
- Medications are labeled
- What needs to be on the label?
MM 05.01.11
- The hospital safely dispenses medications
- Anti-diversion strategies
- How many of you have been around narcotic diversion

MM 05.01.17
- The hospital follows a process to retrieve recalled or discontinued medications

MM 07.01.03
- The hospital responds to actual or potential adverse drug events, significant adverse drug reactions and medications errors.

Post test questions
1. What is the most common TJC citation?
2. What are the two letters which identify pharmacy oriented sections in TJC accreditation manual?
3. How often should you prepare for TJC visits?
4. Managing emergency medications is not covered by TJC?

Resources
- The Joint Commission
  https://www.jointcommission.org/facts_about_joint_commission_accreditation_standards/

340B Audits
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University of Illinois Hospital & Health Sciences System
September 17, 2016
Statement of Conflicts of Interest

I have no actual or potential conflict of interest in relation to this presentation.

I am familiar with the 340B Drug Discount Program (340B Program).

A. Yes
B. No

I am involved with the 340B program.

A. Yes
B. No

340B Program

- Provides covered outpatient drugs to eligible health care organizations at significantly reduced prices.
- Administered by Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA).
- Mandated for drug manufacturers who participate in the Medicaid Drug Rebate Program.
- The 340B Program enables covered entities to stretch scarce Federal resources, reaching more eligible (underserved) patients and providing more comprehensive services.

340B Program Regulations

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Definition</th>
<th>Operational</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPA Database</td>
<td>Maintain accurate covered entity information in OPA database</td>
<td>Review database periodically</td>
</tr>
<tr>
<td>Duplicate Discount Prohibition</td>
<td>Cannot use upfront discounted 340B priced drugs and back-end Medicaid rebate on the same claim</td>
<td>Billing restrictions/requirements with Medicaid fee-for-service claims</td>
</tr>
<tr>
<td>Diversion Prohibition</td>
<td>Law prohibits the resale or transfer of 340B drugs to anyone other than a patient of the covered entity</td>
<td>340B drugs may only be dispensed to 340B eligible patients. Maintain accurate 340B drug inventory</td>
</tr>
</tbody>
</table>

All covered entities have to follow these three regulatory requirements.

340B Controversies

Management of 340B program varies, lack consistency. Negative publicity and lobbying to scale down.

HRSA begins conducting audits in 2012.

Different interpretations of the 340B regulations.
Inventory Management of 340B Drugs

Separate dual physical inventory
- Purchase directly from 340B account
- Non-340B and 340B medications have two different stock bottles

Replenishment (Single inventory)
- Non-340B account: initial purchase of 11-digit NDC
- Split-billing software maintains tally of credits.

University of Illinois Hospital & Health Sciences System

Background:
- Academic teaching hospital: 7 health science colleges
- 495-bed tertiary care hospital, 22 outpatient clinics and 1 FQHC with 11 satellite locations
- Outpatient payer mix: Medicare (22%); Medicaid (16%); Medicaid Managed Care (23%) and self-pay (2%)
- Demographics: African American (48%); Hispanic (6%) and Caucasian (16%)

340B Participation:
- University of Illinois Hospital (DSH) and Mile Square Health Center (FQHC).
- The University of Illinois Ambulatory Care Pharmacies are contract pharmacies for the UI Health covered entities (6 ambulatory pharmacies).
- 340B participation audited by HRSA in October 2015

340B at UI Health

- Unique to our health system...
  - Contract pharmacy arrangement
  - Access to the EMR
  - Work closely with the clinics
  - Decision to fill a prescription with 340B is prospective and is made at the pharmacy level
  - Split-billing system is a combination of homegrown and outside vendor.

HRSA Audit

Audit notice
Authorizing official will receive the audit notification
Audit Documentation Request
Past six months of dispense data Request Policy & Procedure and other documents
On-site Audit
Review of prescriptions for 340B eligibility site visits of hospital and pharmacies
HRSA Findings
1. No findings
2. Findings. Either appeal the findings or accept and provide corrective action plan

Preparatory process for successful 340B audits

Establish comprehensive teams (across the health system and within the pharmacy)

Review 340B Policy and Procedures
340B patient definition eligibility- how is a dispense eligible?
Examine and define system flows and work flows
Inventory management of drugs

Educate key stake holders, providers and staff members
Identify strategies for successful 340B audits

Create a 340B compliance plan
- Use 340B regulation requirements and policy and procedures

Daily
- Review 340B claims and 340B purchases

Monthly
- Audit 340B dispensers for 340B patient definition
- Review Medicaid FFS and Managed Care Claims and split-billing system

Quarterly
- Review information in the CPA database

Yearly
- Review the policies and procedures
- Educate staff with new updates and a review of the 340B Program

As needed
- Split-billing system and accumulators: test the anomalies each time change is made to the logic

Role pharmacy technicians can play in the preparation for an audit

- Assure appropriate inventory management
- Provide insight on workflow practices
- Administer self-audits with pharmacist oversight
- Compile self-audit findings
- Assist with dissemination of audit findings

“Lessons learned” from the audit can be used to improve compliance

- Strong audits = identify potential weaknesses
- Identify appropriate team members to resolve the problem
- Document problem and resolution
- Incorporate practice changes into policy and procedures and educational modules
- Disseminate and review information with other departments within the institution

Corrective Feedback Mechanism

Audit identified potential weakness

<table>
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<tr>
<th>System related</th>
<th>Local practice related</th>
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</thead>
<tbody>
<tr>
<td>Identify appropriate members to assist</td>
<td>Test out the potential resolutions</td>
</tr>
<tr>
<td>Involved staff members review and respond with corrective action plan</td>
<td></td>
</tr>
</tbody>
</table>

| Not appropriate. Test out potential resolution until appropriate solution found |
| Appropriate. Incorporate into P&P and disseminate information |

Case Study

Elizabeth picked up a prescription from one of our pharmacies on 1/8/16; the fill was a 340B drug. This dispense was randomly selected on our monthly 340B audit. The information below is populated from our prescription data entry system. The QI technician reviews the dispense to ensure that it was appropriate to dispense 340B (Diversion Prohibition).

Corrective Feedback Mechanism

Case Study

The QI technician will review and collect information from the EMR to ensure that prescription was an eligible 340B dispense. The information below is completed by the technician and reviewed by the 340B pharmacist.
## Conclusion

For a successful 340B Program:
- Understand the 340B regulations and maintain a compliance plan
- Conduct self-audits to help ensure the system is working
- Technicians have an integral role in maintaining compliance
- Use self-audit findings to correct potential weaknesses

## Which 340B Program regulation requires accurate management of 340B drugs inventory?

A. OPA Database Review  
B. Duplicate Discount Prohibition  
C. Diversion Prohibition  
D. Drug Management Requirement

## Establishing a 340B compliance plan should be based on two key components, the 340B regulation requirements and:

A. Inventory Management Regulation  
B. Feedback from key stakeholders, providers and staff  
C. 340B Policy and procedures  
D. 340B split-billing system

## Pharmacy technicians should be involved in the 340B audit process. One example of the role taken by the technician is:

A. Assisting with inventory management  
B. Overseeing the audits  
C. Act as the authorizing official

## Self-audits are an integral part of 340B compliance, the best use of audits findings is:

A. Maintain records in 3 ring binders  
B. Assist with identifying system weaknesses  
C. Send to HRSA  
D. Review findings but do not disseminate

## Resources

- HRSA  
  - http://www.hrsa.gov/opa/  
- Apexus  
  - https://www.apexus.com  
- 340B Health  
  - http://www.340bhealth.org
References