Regulatory Agencies’ Impact on Health System Pharmacies

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Today’s Objectives

- Which agencies routinely ‘inspect’?
- Why should we care?
- What areas are reviewed?
- Who from pharmacy is involved?

Agencies ‘Inspecting’ Pharmacies

- Board of Pharmacy
- Washington State Department of Health
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
Board of Pharmacy

- All pharmacies shall be subject to periodic inspections to determine compliance with laws regulating the practice of pharmacy. (WAC 246-869-190)

- Three rating classifications
  - Class A – score 90-100
  - Conditional – score 80-90 – grace period 60 days
  - Unsatisfactory – score <80 – grace period 14 days

- Pharmacies receiving an unsatisfactory rating which present a clear and present danger to the public health, safety and welfare will be subject to summary suspension of the pharmacy license.

What does the Board of Pharmacy enforce?

- Washington Administrative Code (WAC)
- Revised Code of Washington (RCW)
- Code of Federal Regulations (CFR)
- Departmental Policy and Procedure Manual (SOP)

WSBOP Inspections

- General Requirements
- Patient Health and Safety Requirements
- Professional Requirements
- Facilities
### General Requirements (10 points)
- Inspection Certificate and Pharmacists’ licenses displayed to the public
- Pharmacy location license
- DEA certificate of registration
- Staff list

### Patient Health & Safety Requirements (30 points)
- Patient medication record includes allergies and chronic conditions
- Patient education requirements
- Child resistant containers
- Poison Control
- No expired medications

### Professional Requirements (40 points)
- Controlled substances
  - DEA Form 222
  - Biennial inventory of controlled substances
  - Storage
- References, including Pharmacy Lawbook
- Pharmacy Ancillary Personnel
- Pharmacist’s Professional Responsibilities
- Labeling requirements
- Prescription record requirements
- Regulation compliance for pharmacies required to have policies and procedures
Facilities (20 points)

- Adequate security for medications
- Restricted access to pharmacy
- Environment
  - General cleanliness
  - Sinks, counterspace
  - Refrigerators
- Necessary Equipment

Joint Commission on Accreditation of HealthCare Organizations (JCAHO)

Mission: To continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

JCAHO

- Accredits more than 15,000 health care organizations in the U.S.
- Surveys can last from one to five days, depending on the facility and type of services provided.
- Generally three surveyors: Administrator, Physician, Nurse
Benefits of JCAHO Accreditation

- Leads to improved patient care.
- Demonstrates organization’s commitment to safety and quality.
- May substitute for federal certification surveys for Medicare and Medicaid.
- Helps secure managed care contracts.
- Enhances organization’s image to the public, purchasers and payers.
- Strengthens community confidence.

The New JCAHO Survey Process

- Assesses compliance with JCAHO standards using tracer methodology

Tracer Methodology

- Traces a number of randomly selected patients through the organization’s entire health care process, in the sequence they receive care
- The recipient of care is referred to as a ‘tracer.’
- Surveyors use the facility’s Clinical Service Groups to identify tracer patients from the active patient list

Priority Focus Areas

- Assessment and Care/Services
- Communication
- Credentialed and Privileged Practitioners
- Equipment Use
- Infection Control
- Information Management
- Staffing
- Medication Management
Priority Focus Areas

- Organizational Structure
- Orientation and Training
- Patient Rights and Ethics
- Physical Environment
- Quality Improvement Activity
- Patient Safety
- National Patient Safety Goals (NPSG)

Examples of Clinical Service Groups

- Cardiology
- Orthopedics
- Obstetrics
- Oncology
- Neurology
- Psychiatry
- Rehabilitation

How do surveyor's plan the survey?

- Performance Improvement Data
- List of departments/areas/services
- List of medications that organization considers high risk
- List of active patients who are on one or more high risk medications, including patient’s diagnosis and location
Previous Survey Process vs. Tracer Methodology

Previous
• Volume driven & structured around patient care areas
• Unit visits 'scheduled' in advance
• Manager level participation
• Focused on policies and procedures

Tracer Method
• Process driven
• Customized to the organization
• Surveys continuum of services
• Multi-level participation of staff
• Focused on actual delivery of care

Patient Tracers
• Assess relationships between disciplines, departments, programs, etc.
• Evaluate performance of processes, focusing on integration and coordination
• Observation of direct patient care, including medication management
• Review medical record with staff

Medication Management System Tracer
• Selecting, procurement, storage, prescribing, ordering, transcribing, dispensing, administration, monitoring
• Evaluates continuity of medication management processes
• Establishes baseline of organization’s compliance with standards
• Use group discussions, record review, staff query, direct observation
MM System Tracer

- Is patient information accessible?
- Are medications stored securely?
- Does policy for documentation of diagnosis and indication for use match practice?
- Are orders legible, transcribed accurately, with all required elements included?
- Are abbreviations appropriate?
- What precautions are in place for look-alike, sound-alike medications?

MM System Tracer

- Policies exist and are followed for use of range orders, PRNs, hold orders, titrations and herbal medications?
- Verbal order policy – v.o.r.v.
- Pharmacist review of first doses of medications OVERRIDE policy
- Medications are dispensed in most ready to use form
- Multi-dose vials are labeled appropriately

MM System Tracer

- Medication Administration
- What are the processes for safe use of high risk medications?
- Is there a process for monitoring response to first dose of new medications?
- Review of ADRs and medication errors
  - tracking, trending, PI, education
Sample MM Tracer Questions

- Are all medications that the patient was taking at home noted in the medical history?
- Does the medication administration record match the orders in patient’s chart?
- How do you get information about the patient to evaluate the medication plan?
- What education did the patient receive about their medications?

Survey Results

Elements of Performance scored as follows:

0  Insufficient compliance
1  Partial compliance
2  Satisfactory compliance
NA Not Applicable

Survey Results

Surveyors ordinarily limit their evaluation of track record of compliance to 12 months. This time frame may be shorter or longer depending on the circumstances.

Scores:
0  Fewer than 6 months
1  6-11 months
2  12 consecutive months
JCAHO Accreditation

- Accredited
- Provisional Accreditation
- Conditional Accreditation
- Preliminary Denial of Accreditation
- Denial of Accreditation
- Preliminary Accreditation

Objectives achieved?

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Questions?