Navigating the Regulatory Alphabet Soup
Dave Lacknauth, Pharm D., MBA, MS

Objectives - Pharmacists
- Review the major regulatory bodies and policies affecting institutional pharmacy practice
- Analyze barriers to successful compliance with regulatory requirements
- Evaluate proactive measures to enhance institutional pharmacy compliance to policies and regulation

Objectives - Technicians
- Review the major regulatory bodies and policies affecting institutional pharmacy practice
- Describe the roles of technicians in maintaining compliance with regulatory requirements

Role of the governing body
- Payer for service provided
- Validator of service provided
- Regulatory body inspecting rules regulations
- Best practice and improvement role

Major Regulatory Bodies
- CMS
- TJC
- URAC
- ACHA
- DOH
- OSHA/DOT
- USP
- DSCA
- 340B
- HRSA
- RFP
- ISMP

CMS: Centers for Medicare and Medicaid Services
- **Payer** - pay for services
  - Private payers
  - Validate quality of the service
  - Pay for performance
  - HCAHPS scores for patient satisfaction
  - Readmission penalties
**TJC: The Joint Commission**

- Accrediting body
- Must be accredited for payment
- Hospital:
  - Choice of accrediting body

**TJC Major Competitors**

- HFAP: Healthcare Facilities Accreditation Program
- DNV: Det Norske Veritas Healthcare, Inc.

**URAC: Utilization Review Accreditation Commission**

- Accreditation: 2 – 3 years
- Types of organizations accredited:
  - Community Pharmacy
  - Mail Pharmacy
  - Specialty Pharmacy
  - Drug Therapy Management
  - Pharmacy Benefit Management

**AHCA: Agency for Healthcare Administration**

- Responsibilities (cont.):
  - Medicaid program administration
  - Contract administration with Florida Healthy Kids Corporation
  - Health maintenance organizations & prepaid clinic certifications
  - Other duties prescribed by statute or agreement

- Inspect facilities, ensures standards met
  - Fire safety, employee safety, patient safety
  - Not met: potential for shut down
DOH: Department of Health

- Protects public health & safety
- Board of Pharmacy
- Headed by a state surgeon general
- Reports to the governor

USP 797/USP 800

- USP 797
  - Non-sterile drug compounding
  - E.g. ointments, liquids
- USP 800
  - Requirements for hazardous drugs
  - Sterile or non-sterile
  - E.g. chemotherapy, radiopharmaceuticals

DSCA: Drug Quality and Security Act

- Confirm entities are licensed/registered:
  - Registration:
    - Manufacturers
    - Repackers
  - Licensing:
    - Wholesale distributors
    - Third-party providers
    - Pharmacies
- Identify and trace prescription drugs
- Protects consumers from:
  - Counterfeit, stolen, contaminated, or harmful drugs
- Improves detection/removal of dangerous drugs

340B: Drug Discount Program

- U.S. Federal Government Program
- Drug manufacturers:
  - Provide drugs at reduced prices
  - Qualifying hospitals
340B: Drug Discount Program

- 6 Hospital Types Covered:
  - Disproportionate share hospitals (DSHs)
  - Children's & cancer hospitals exempt from Medicare payment system
  - Sole community hospitals
  - Rural referral centers
  - Critical access hospitals (CAHs)

- Hospitals must be:
  - Owned/operated by state/local government
  - Public/private non-profit corporation with governmental powers
  - Contract with a state/local government
  - Provide care to low-income individuals

HRSA

- Tens of millions of Americans receive quality, affordable health care and other services through HRSA’s 90-plus programs and more than 3,000 grantees.

- 340B governance

RFP: Request for Proposal

- Bidding solicitation
- Drives down price
- Increase competition
  - Vet out vendors in a fair manner
  - Prevents bias
  - Good business practice

ISMP: Institute for Safe Medication Practices

- Nonprofit organization
- Prevention of medication errors
- Safe medication use
- Disseminates adverse drug information:
  - Health care professionals
  - Institutions
  - The public
- Operates Medication Errors Reporting System

Barriers to successful compliance with regulatory requirements

- Communication gaps between departments
- Lack of multidisciplinary process improvement
- Communication to administrative teams with cost benefit outline
Barriers to successful compliance with regulatory requirements

- Financial barriers
- Lack of knowledge
- Lack of project planning
- Relationships

Measuring compliance

- Sterility testing results
- Clinical interventions around targeted areas
- HCPS scores specific to targeted areas

Measuring compliance

- Medication error trending
- Policy and procedure process
- Gap analysis reviewed at a defined frequency

References