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Navigating the Regulatory Alphabet Soup

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Break Through 

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

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Objectives - Technicians

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

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Role of the governing body

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

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Major Regulatory Bodies

• CMS	• USP
• TJC	• DSCA
• URAC	• 340B
• ACHA	• HRSA
• DOH	• RFP
• OSHA/DOT	• ISMP

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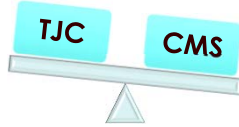
CMS: Centers for Medicare and Medicaid Services

- **Payer** – pay for services
 - Private payers
- Validate quality of the service
 - Pay for performance
 - HCAHPS scores for patient satisfaction
 - Readmission penalties

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TJC: The Joint Commission

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



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TJC Major Competitors

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



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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

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AHCA: Agency for Healthcare Administration



- Responsibilities:
 - Licensure, inspection, & regulatory enforcement
 - Consumer complaints investigation
 - Implementation of Certificate of Need program
 - Operation of FL Center for Health Information & Policy Analysis

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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

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AHCA: Agency for Healthcare Administration



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

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DOH: Department of Health

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

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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

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DSCA: Drug Quality and Security Act

- Confirm entities are licensed/registered:
 - Registration:
 - Manufacturers
 - Repackagers
 - Licensing:
 - Wholesale distributors
 - Third-party providers
 - Pharmacies

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DSCA: Drug Quality and Security Act

- Identify and trace prescription drugs
- Protects consumers from:
 - Counterfeit, stolen, contaminated, or harmful drugs
- Improves detection/removal of dangerous drugs

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DSCA: Drug Quality and Security Act

- Receive, store, & provide tracing documentation:
 - Transaction information, history, statements
 - Store documents: 6 years
 - Selling to trading partner:
 - Generate & provide all tracing documents

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340B: Drug Discount Program

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

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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)



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340B: Drug Discount Program

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



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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




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RFP: Request for Proposal

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



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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



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Barriers to successful compliance with regulatory requirements

- Communication gaps between departments
- Lack of multidisciplinary process improvement
- Communication to administrative teams with cost benefit outline



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Barriers to successful compliance with regulatory requirements

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

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Measuring compliance

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

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Measuring compliance

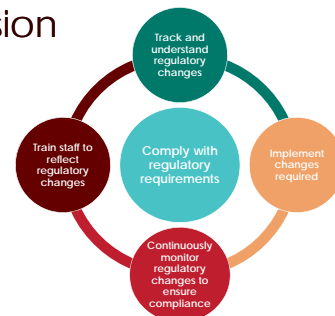
- Medication error trending
- Policy and procedure process
- Gap analysis reviewed at a defined frequency

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Conclusion



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