DeBunking Pharmaceutical Myths

Understanding the Changes
In Pharma Management

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Objectives

Value of a consultant pharmacist
DEA challenges
Facility vs Medical Director DEA license
Compounding Pharmacies 503A 503B
TJC AAAHC CDPHE expectations
USP 797 USP 800

Compounding Pharmacies

503A

- Compound according to prescriptions specific to a particular patient.
- State boards of pharmacy govern
- Comply with USP and other guidelines

503B

- Patient specific medications
- Held to higher regulatory standards
- Requires maintaining full compliance with current good manufacturing practices (CGMP)

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Compounding Pharmacies

503A

- Licensed by state
- *Must Comply with USP 795, 797, 800 along with state board of pharmacy regulations*

503B

- Licensed by state and FDA
- *Must Comply with USP 795, 797, 800 along with state board of pharmacy regulations* ***and 21 CFR Part 210 and 211 (CGMP)***

Compounding Pharmacies

Challenges

- Maintain quality reports
- FDA inspections
  - Item recalls
  - Facility recalls
    - RXG
    - Pharmedium
- Research

Compounding Pharmacies

- FDA requires a prescription for each patient from a 503A compounding pharmacy
- FDA requires a prescription for each patient from a 503B compounding pharmacy
- 503A pharmacy must follow Good Manufacturing Practices

Drug Enforcement Administration

Challenges

- Biennial Inventory
- Controlled Substances Ordering System (CSOS)
- 222 form completion and log
- Diversion
- Facility specific DEA registration
  - Medical Director
  - Facility

Drug Enforcement Administration

- Biennial inventory is required every six months
- 222 form numbers are required to be logged like a check register.
- A Percocet tablet is missing, diversion is not suspected. Diversion report to DEA is required
- CDPHE offers guidance in reporting diversions

Accreditations

TJC

- Medication error prevention
  - High Alert
  - Look alike Sound Alike
- Mfg recommended storage
- Authorized access to meds
- Labeling, exp dates, warnings
- Sample meds
- Emergency meds readily available

AAAHC

- Follow national standards
- Infection Control
  - CDC Multidose / Single dose vials
- Proper storage and use of multidose vials
- Recall policies

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AAAHC

CDPHE

- Drug Diversion Reporting
- Hazardous Medication Waste
- Controlled Drug waste
- Infection Control
  - SDV, MDV, Patient Care Area
  - Drug Diversion
    - Chart review
- Expired meds
- Glucometer
  - More than one patient use
  - Test solutions
- Pregnancy test

TJC, AAAHC, CDPHE

- All consider using a Multidose vial as a single dose vial in surgery as an infection control issue not being followed adequately
- All consider expired drugs an issue
- Only TJC considers LASA drugs an issue

United States Pharmacopeia

- Official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products
- Sets standards for the quality of drug products and works with healthcare providers to help them meet the standards.
- Standards have same relevance as regulations

- Applies to all healthcare settings
- USP 797 USP 800
  - Greatest significance to ASCs

United States Pharmacopeia

USP 797

- Single Dose vs Multidose vials
  - SDV
    - One time / One Patient
  - MDV (CDC)
    - SDV in patient care area
    - 28 days in non patient care area
- Compounding
  - Immediate use
  - Up to three sterile products

USP 800

- Protect workers, patients and general public
- Facilities where hazardous drugs (HDs) are prepared.
- Includes pharmacists, technicians, nurses, physicians, physician assistants.
- Mitomycin
- December 2019

United States Pharmacopeia

USP 800 – Mitomycin C

- Primarily pharmacy compounding
- All healthcare aspects
  - Training – annual competency
  - Proper environmental equipment, garb, etc
    - Closed system transfer devices - Mitosol
    - Goggles
    - Chemo resistant gown
    - Shoe and hair covers
  - Proper cleanup
  - Proper disposal

United States Pharmacopeia

- USP 797 allows nurses to mix four sterile drugs in the OR
- USP 800 requires annual competencies and will become effective December 1, 2019
- USP 800 applies to pharmacies only

Facility DEA registration
Other Outlet Pharmacy License

- Requires a consultant pharmacist
- Removes responsibility from medical director to the facility and consultant pharmacist
- Depending on the consultant pharmacist
  - Increased monitoring of medication management
  - More frequent contact and guidance concerning medication management
  - Risk Mitigation

Facility DEA Registration

- A special pharmacy license is not required to apply for a facility DEA registration.
- Convalescent Centers require a DEA registration separate from the ASC
- A designated nurse is authorized to sign and order schedule ii drugs

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