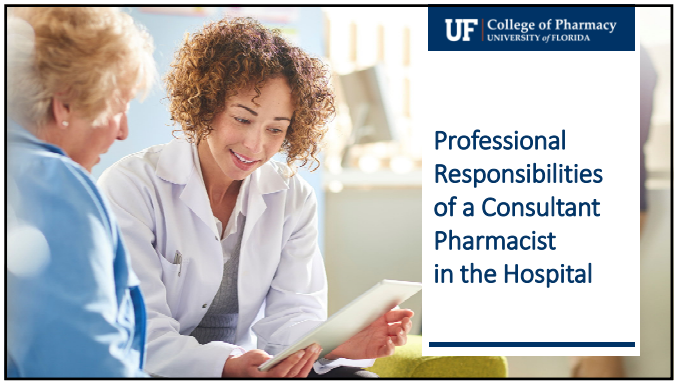

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Professional Responsibilities of a Consultant Pharmacist in the Hospital

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Disclosure Statement

Norman Pillsbury, Pharm.D., BCPS has disclosed that she has no relevant financial disclosures. No one else in a position to control content has any financial relationships to disclose.

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The University of Florida College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

ACPE

Objectives

At the completion of this activity, the participant will be able to:

- Summarize the professional responsibilities of a consultant pharmacist in the hospital setting
- Describe the responsibilities of the consultant pharmacist in the delivery and reporting of information to insure patient safety
- Describe the role of the consultant pharmacist in creating medication safety systems policies and procedures.
- Describe role of the consultant pharmacist in the creation and support of safe and efficient medication distribution systems

Responsibilities of a Consultant Pharmacist in a Hospital Setting

- Chapter 465, F.S., requires all institutional pharmacies to be under the professional supervision of the consultant pharmacist of record licensed in the State of Florida.

Florida Board of Pharmacy. Institutional Pharmacy Permit. https://floridaspharmacy.gov/licensing/institutional-pharmacy-permit/

Responsibilities of a Consultant Pharmacist in a Hospital Setting.

- See Handout: State of Florida Department of Health Investigative Services Class II & III Institutional Pharmacy (INV 361)
- See Handout: State of Florida Department of Health Investigative Services Sterile Compounding (INV797)

Florida Board of Pharmacy. Institutional Pharmacy Permit. https://floridaspharmacy.gov/licensing/institutional-pharmacy-permit/

State of Florida Department of Health Investigative Services INV 361 - Class II & III Institutional Pharmacy

- Current professional supervision of a consultant pharmacist.
- Current DEA registration.
- Pharmacists, interns and technicians have proof of current licensure.

FORTUNE: Fake Walgreens Pharmacist Alleged to Have Filled 750,000 Prescriptions

January 31, 2019

The company slogan read "Walgreens. Trusted Since 1901". That claim, however, may have just taken something of a dent — particularly, if you've used a Bay Area Walgreens (WBA) in the past decade…

Dobush, G. Fake Walgreens Pharmacist Alleged to Have Filled 750,000 Prescriptions. https://fortune.com/2019/01/31/walgreens-fake-pharmacist-prescription/. Published January 31, 2019.

State of Florida Department of Health Investigative Services INV 361 - Class II & III Institutional Pharmacy

- Controlled substance records are readily retrievable.
- Controlled substance records are maintained for 4 years.

State of Florida Department of Health Investigative Services INV 361 - Class II & III Institutional Pharmacy

- DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable.
- Controlled substance inventory taken on biennial basis and available for inspection.

State of Florida Department of Health Investigative Services INV 361 - Class II & III Institutional Pharmacy

- Policy and procedures for removal of a single dose of medication for administration to a patient when no pharmacist is on duty.
- All prepacking, either unit dose or multiple dose, is done in accordance with policies and procedures set up by consultant pharmacist.

State of Florida Department of Health Investigative Services INV 361 - Class II & III Institutional Pharmacy

- Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed.

State of Florida Department of Health Investigative Services INV 361 - Class II & III Institutional Pharmacy

- Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection.

State of Florida Department of Health Investigative Services INV 361 - Class II & III Institutional Pharmacy

- Policies and procedures for decentralized automated medication system and criteria for determining medications that qualify as override medications.
- Pharmacy has a quality assurance program for automated medication system that provides for a review of overrides, investigation of medications error related to the automated medication system and review of discrepancies and transaction reports.

State of Florida Department of Health Investigative Services Sterile Compounding (INV797)

- Low Risk
- Medium Risk
- High Risk
- Sterility Testing (Outsourced and On site)
- Endotoxin Testing
- Immediate Use Compounding

State of Florida Department of Health Investigative Services Sterile Compounding (INV797)

- Single/Multiple Use Container BUD
- Hazardous Drugs
- Facility Design and Certification
- Isolators
- Facility Design and Certification (Secondary Engineering Controls)
- Quality and Control

State of Florida Department of Health Investigative Services Sterile Compounding (INV797)

- Personnel Cleansing, Garbing & Competency Evaluation
- Verification
- Dispensing/Distribution
- Policy/Procedure
- Radiopharmaceuticals
- Miscellaneous
- Special Parenteral Enteral & Extended Scope

Drug Information

- Florida Administrative Code 64B16-27.1001 lists the following functions as elements of the practice of Pharmacy:
  - (e) Engage in professional communication with practitioners, nurses or other health professionals.
  - (f) Advise or consult with a patient, both as to the prescription and the patient profile record.

Florida Administrative Rules, Law, Code, Register. 64B16-27.1001- Florida Administrative Code.
https://www.flrules.org/gateway/ruleNo.asp?id=64B16-27.1001

Drug Information

- INV797:
  - 108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]

Florida Department of Health. State Of Florida Department Of Health Investigative Services. http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-programs/_documents/florida-cmpd-form.pdf

Development of Pharmacy Practice

Florida Statutes 465.003(13) defines Pharmacy Practice as:

"Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy.

The Florida Legislature. The 2019 Florida Statues: Regulation of Professions and Occupations Pharmacy. http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0400-0499/0465/Sections/0465.003.html

Assessment Question

Pharmacy Practice, as defined in Florida Statutes 465.003, includes which of the following?

A. Compounding

B. Dispensing

C. Consulting pursuant to a prescription or order

D. Consulting independent of any prescription or order

E. All of the above

Assessment Question

Pharmacy Practice, as defined in Florida Statutes 465.003, includes which of the following?

A. Compounding

B. Dispensing

C. Consulting pursuant to a prescription or order

D. Consulting independent of any prescription or order

E. All of the above

Assessment Question

Florida Statutes 465.003(13) defines Pharmacy Practice as: "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services.

Development of Pharmacy Practice

- *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)* published by Joint Commission Resources has a chapter entitled Medication Management. This chapter lists standards that are based on the Pharmaceutical Services section of the Medicare Conditions of Participation.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.ohtmhouse.com/Nbd/Products/Book.aspx?sku=163585083D

IV Admixture Services

- INV 361
  - A pharmacist is conducting the compounding or is physically present and gives direction to the registered pharmacy technician for reconstitution, addition of additives, or for bulk compounding of the parenteral solution. [64B16-27.1001(2) F.A.C.]
  - Florida licensed pharmacist certifying the final parenterals, and bulk solutions and medication orders and documenting processing so that professional responsibility can be traced to a pharmacist. [64B16-27.1001(2), F.A.C] [64B16-27.1001(3) F.A.C]

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=1635850630

IV Admixture Services

- INV797
  - Immediate Use, Low Risk, Medium Risk, High Risk
    - Determine this accurately

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=1635850630

IV Admixture Services

- INV797
  - Hazardous Drugs
    - A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room.
    - Personnel compounding hazardous drugs wear appropriate personal protective equipment
    - Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available.
    - Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=1635850630

IV Admixture Services

- INV797
  - Hazardous Drugs
    - Access to hazardous drug preparation areas is limited to authorized compounding personnel.
    - Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available.
    - Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs.
    - Facility maintains appropriate disposal containers for all hazardous waste.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O

IV Admixture Services

- INV797
  - Personnel Cleansing, Garbing & Competency Evaluation
    - USP <797> Appendix III Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel
    - USP <797> Appendix IV Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O

Medication Safety

- **MM.01.01.03** The hospital identifies, in writing, its high-alert and hazardous medications.
- **MM.01.02.01** The hospital addresses the safe use of look-alike/sound-alike medications.
- **MM.02.01.01(6)** The hospital standardizes and limits the number of drug concentrations available to meet patient care needs.

Medi-Dose EPS. Pharmacy Auxiliary Labels. https://www.medidose.com/Pharmacyauxiliarylabels.aspx

Medication Safety

- **MM.02.01.01(9)** Medications designated as available for dispensing or administration are reviewed at least annually based on emerging safety and efficacy information.
- **MM.04.01.01(2)** The hospital has a written policy that defines the following: Actions to take when medication orders are incomplete, illegible, or unclear.
- **MM.05.01.01** A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital.

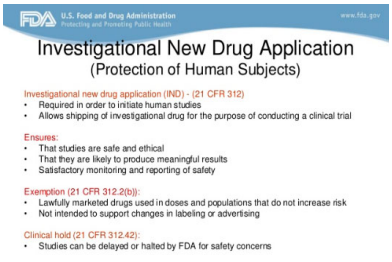
Medication Safety

- **MM.05.01.11** The hospital safely dispenses medications.
- **MM.06.01.01** The hospital safely administers medications.
- **MM.06.01.03** Self-administered medications are administered safely and accurately.

Medication Safety

- MM.06.01.05 The hospital safely manages investigational medications.

Medication Safety



Medication Safety

- Pediatric Dosage Forms
- MM.03.01.01(10) Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit doses that have been repackaged by the pharmacy or a licensed repackager.
- MM.04.01.01(10) The hospital defines, in writing, the circumstances for which weight-based dosing is required for pediatric populations.

Medication Safety

- Geriatric Dosage Forms
- MM.03.01.01(10) Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit doses that have been repackaged by the pharmacy or a licensed repackager.

Medication Safety

- Sterile Dosage Forms
- INV797
- MM.05.01.07(1) A pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product's stability is short.

Assessment Question

Under what two circumstances does MM.05.01.07(1) permit compounding or admixture of a sterile compounded product by someone other than a pharmacist or pharmacy staff under the supervision of a pharmacist?

Assessment Question

1. Urgent situations in which a delay could harm the patient
2. When the product's stability is short.

IV solutions containing 30 mg/mL (20 mg of ampicillin and 10 mg of sulbactam per mL) in 5% dextrose injection are stable for **2 hours at 25°C or 4 hours** when refrigerated at 4°C; those containing 3 mg/mL (2 mg of ampicillin and 1 mg of sulbactam per mL) are stable for 4 hours at 25°C.1.

Source: Drugs.com

Medication Safety

- **Accurate Prescription Order Entry**
- **MM.04.01.01** Medication orders are clear and accurate.
- **MM.04.01.01(2)** The hospital has a written policy that defines the following: The required elements of a complete medication order.
- **MM.04.01.01(2)** The hospital has a written policy that defines the following: The precautions for ordering medications with look-alike or sound-alike names.

Joint Commission Accreditation. 2019 Comprehensive Accreditation Manual for Hospitals (CAMH). JCR Publishing; 2019.
https://www.ritterhouse.com/Rbd/Products/Book.aspx?sku=163585063O

Medication Safety

- **Accurate Prescription Order Entry**
- **MM.04.01.01(2)** The hospital has a written policy that defines the following: Actions to take when medication orders are incomplete, illegible, or unclear.
- **MM.04.01.01(6)** The hospital minimizes the use of verbal and telephone medication orders.
- **MM.04.01.01(8)** The hospital prohibits summary (blanket) orders to resume previous medications.

Joint Commission Accreditation. 2019 Comprehensive Accreditation Manual for Hospitals (CAMH). JCR Publishing; 2019.
https://www.ritterhouse.com/Rbd/Products/Book.aspx?sku=163585063O

Adverse Drug Reactions

- **Screening**
  - **INV797 113.** Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]
  - **MM.07.01.03(1)** The hospital has a written process to respond to actual or potential adverse events, significant adverse drug reactions, and medication errors.

Joint Commission Accreditation. 2019 Comprehensive Accreditation Manual for Hospitals (CAMH). JCR Publishing; 2019.
https://www.ritterhouse.com/Rbd/Products/Book.aspx?sku=163585063O

Adverse Drug Reactions

- Reporting
  - INV 361 Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.]

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019.
https://www.ritterhouse.com/RitaProductsTBook.aspx?sku=1615050630

Adverse Drug Reactions

- Reporting
  - MM.07.01.03(3) The hospital complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019.
https://www.ritterhouse.com/RitaProductsTBook.aspx?sku=1615050630

Case Study

- A 60-year old male is transferred to the med-surg unit postop. He has a fentanyl epidural in place for the management of postoperative pain.
- A nurse performs a pain assessment and the patient complains of pain of 8-9 on a scale of 0-10. The nurse calls the hospitalist and obtains an order for morphine 4 mg iv once for severe pain.
- The medication is taken out of the automated dispensing cabinet on override and administered.

Case Study

- Any thoughts from the audience about what might have prevented this?

Case Study

- Twenty minutes later the patient is found unresponsive and naloxone is administered.
- The patient responds to the naloxone.
- The pharmacist on the rapid response team discovers that the nurse failed to review an order from anesthesia that indicated, "No opioids, benzodiazepines, or other respiratory depressants to be given while the epidural is in place or for twelve hours after it is removed unless ordered by anesthesia."

Drug Interactions

- Screening
  - MM.02.01.01(2) The hospital develops and approves criteria for selecting medications, which, at a minimum, include the following:
    - Indications for use
    - Effectiveness
    - Drug interactions
    - Potential for errors and abuse
    - Adverse drug events
    - Sentinel event advisories
    - Population(s) served (for example, pediatrics, geriatrics)
    - Other risks
    - Costs

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Drug Interactions

- Screening
  - MM.05.01.01(4) All medication orders are reviewed for the following: Existing or potential interactions between the medication ordered and food and medications the patient is currently taking.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O

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Drug Interactions

- Reporting
  - INV 361 Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.]

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O

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Manufacturing

- Current Good Manufacturing Practices (CGMPs)
  - CGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA.
  - The main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (CGMPs) regulation for human pharmaceuticals.

U.S. Food & Drug Administration. Facts About the Current Good Manufacturing Practices (CGMPs). https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps. Updated June 25, 2018

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Manufacturing

- The Drug Quality and Security Act (DQSA)
  - The Drug Quality and Security Act, signed into law on November 27, 2013, created a new section 503B in the Federal Food, Drug, and Cosmetic Act. Under section 503B, a compounder can become an outsourcing facility.
  - Outsourcing facilities:
    - must comply with CGMP requirements;
    - are inspected by FDA according to a risk-based schedule; and
    - must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

U.S. Food & Drug Administration. Information for Outsourcing Facilities. https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities. Updated January 2, 2019.

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Packaging

- INV 361
  - All prepacking, either unit dose or multiple dose, is done in accordance with policies and procedures set up by consultant pharmacist. [64B16-28.120(3) F.A.C.].
  - Prepacking and labeling of unit dose or multiple dose medication is checked by Florida licensed pharmacist. [64B16-28.608(4) F.A.C.]

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=1635850630

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Labeling

- INV 361
  - Unit dose medication is properly labeled. [61N-1.006(1)(a) F.A.C.]; [64B16-28.108(3) F.A.C.]
  - Prepacking and labeling of unit dose or multiple dose medication is checked by Florida licensed pharmacist. [64B16-28.608(4) F.A.C.]

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=1635850630

Labeling

- MM.05.01.09 Medications are labeled
  - Elements of Performance
    1. Medication containers are labeled whenever medications are prepared but not immediately administered.
    2. Information on medication labels is displayed in a standardized format, in accordance with law and regulation and standards of practice.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O

Labeling

- MM.05.01.09 Medications are labeled
  - Elements of Performance
    1. All medication prepared in the hospital are correctly labeled with the following:
       - Medication name, strength, and amount (if not apparent from the container).
       - Expiration date when not used within 24 hours.
       - Expiration date and time when expiration occurs in less than 24 hours.
       - The date prepared and the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O

Labeling

- MM.05.01.09 Medications are labeled
  - Elements of Performance
    7. When preparing individualized medications for multiple patients, the label also includes the following:
       - The patient's name.
       - The location where the medication is to be delivered.
       - Directions for use and applicable accessory and cautionary instructions.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019. https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O

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Labeling

- MM.05.01.09 Medications are labeled
  - Elements of Performance
    10. When an individualized medication(s) is prepared by someone other than the person administering the medicine, the label includes the following:
        - The patient's name
        - The location where the medication is to be delivered
        - Directions for use and applicable accessory and cautionary instructions.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019. https://www.ritterhouse.com/RitaProducts/Book.aspx?sku=1619585630

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Transferring

- INV797
  - Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH).* JCR Publishing; 2019. https://www.ritterhouse.com/RitaProducts/Book.aspx?sku=1619585630

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Transferring

- Drug Supply Chain Security Act (DSCSA)
  - The purpose of the DSCSA was to create an electronic system to track and trace certain prescription drugs in the United States. The law regulates transactions between dispensers, pharmacies, manufacturers, repackagers, wholesale distributors, third-party logistics providers, and trading partners.
  - Key provisions:
    - Products must be tracked and traced so that there is a step-by-step account of every entity that has been in possession of the product.
    - Products must be verified as legitimate and unaltered.
    - Products that are suspect must be quarantined and investigated.

King, C., Fink III., JL. What Are the Drug Supply Chain Security Act's Key Provisions? *Pharmacy Times.* https://www.pharmacytimes.com/publications/issue/2017/november2017/what-are-the-drug-supply-chain-security-acts-key-provisions

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Transferring

- MM.03.01.01(4)
  - The hospital has a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, security, disposition, and return to storage.

Joint Commission Accreditation. *2019 Comprehensive Accreditation Manual for Hospitals (CAMH)*. JCR Publishing; 2019.
https://www.rittenhouse.com/Rbd/Products/Book.aspx?sku=163585063O