Pharmacy Compliance in the ASC

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Learning Objectives

- Identify the requirements for handling sterile pharmaceuticals in the ASC environment
- Explain the regulatory aspects of handling and documenting controlled substances in the ASC
- Points of emphasis

Rule Compliance is Stimulating
Biography

- Christopher M. Dembny R.Ph.
- Licensed pharmacist in Texas for > 30 years
- Consultant Pharmacist for surgery centers for > 20 years
- Currently consulting for > 75 ASC
- Current Member of the Texas State Board of Pharmacy

Handling Sterile Pharmaceuticals

- Infection control is a hot topic among all of the regulatory and accreditation agencies.
- Infections are a major problem in hospitals
- Hospital-Acquired Infections Cost $10 Billion a Year: Study — US News 9/3/13
- One out of every 20 patients who are admitted to a hospital will fall victim to an infection they pick up while there, according to the U.S. Centers for Disease Control and Prevention
- --- (US News 9/3/13)

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- Any infection control nurses out there??
- Any centers with a 5% infection rate?
- If so, ....................
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• Four surgeons performed more than 10,000 orthopaedic surgeries in a multispecialty and single specialty ambulatory setting over 8 years. These procedures were reviewed for postoperative deep infection within one year of initial operation.

• (US News 9/3/13)

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• RESULTS:
  • The post-surgical deep infection rate in a multi-specialty ASC was 0.81% in 2867 operations compared with a rate of 0.38% in 7311 operations performed in a single specialty ASC (p = 0.007).
  • PubMed: J Orthop 9/5/13

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• This example isn’t there to show that single specialty centers are better, but to show the difference between hospitals and ASCs.
• Not a fair comparison
• SVD
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This is a broad and confusing issue for many centers.
Information falls into two categories:
A. manufactured sterile products
B. compounded sterile products.

Manufactured Sterile Products:
A. Single dose vials
B. Multiple dose vials

Single dose vials
Has no preservative
Will be labeled: single dose; single patient; preservative free; PF; MPF
The only exception is if you have a USP 797 compliant hood and room and repackage in compliance with USP 797 (almost NONE of you have this). It can be done by a USP 797 compliant pharmacy.
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A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/procedure/injection. (AAAHC)

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Single dose vials
If a single-dose/single-use vial must be entered more than once during a single procedure for a single patient to achieve safe and accurate titration of dosage, use a new needle and new syringe for each entry.” (TJC)

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Single dose vials
Administering drugs from one SDV to multiple patients without adhering to USP <797> standards is not acceptable under CMS infection control regulations. (CMS)

NOT NEGOTIABLE
CMS – propofol DG
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Single dose vial questions?

Multi dose vial

A multi-dose vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative.

Preservative prevents the growth of bacteria.

Does not kill bacteria.

Does not have any effect on virus or fungi.

Should be labeled as multi-dose vial.
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- Multi dose vial
- Disinfect the vial's rubber septum before piercing by wiping (and using friction) with a sterile 70 percent isopropyl alcohol," ethyl/ethanol alcohol, iodophor." or other approved antiseptic swab.
- Allow the septum to dry before inserting a needle or other device into the vial. (TJC)

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- Multi dose vial
- Once a multiple-dose vial is punctured, it should be assigned a "beyond-use" date. The beyond use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer. (TJC)

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- Standard of practice is to label vials with “beyond use date”
- Not date opened.
- TJC specifies using beyond use date.
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- Multi-dose medication vials used for more than one patient are stored appropriately and do not enter the immediate patient care area (e.g., operating room, anesthesia carts).
- This is a point of emphasis on every survey!!!! Insulin-Romazicon-etc

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- NOTE: If multi-dose vials enter the immediate patient care area, they must be dedicated for single patient use and discarded immediately after use.
- The previous 2 slides are copied directly from the CMS infection control worksheet.

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- Not every surveyor understands this
- Not every speaker understands this.
- Thus, the exact verbiage is on the previous slides.
- Verbiage has changed several times to eliminate ambiguity.
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Questions on Multi-dose vials?

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- Compounded sterile products:
  - How many of you compound sterile products in your ASC?
  - Definition of Compounded Sterile Product

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- Low risk compounding
  - Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.
  - USP 797
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- Demerol and Phenergan
- Sterile water and Ancef
- Bupivicaine and hyaluronidase
- Lidocaine and sodium bicarbonate
- BSS and antibiotic
- Should we re-ask the question?
- And: Does anyone have a laminar flow hood?

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- Compounded sterile products (CSP) in the ASC are governed by USP 797.
- USP is recognized as a standards organization and its publication has been adopted by CMS.
- USP 797 is a long publication which you don’t want to study enough to comprehend and can’t comply with in the ASC.
- EXCEPT:

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- USP 797 Immediate Use Exemption
  - Compounded sterile products are exempted from all other requirements of USP 797 if administration is begun to the patient within 1 hour of mixing and continues no longer than 24 hours.
- USP 797
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- Immediate Use Exemption
- For the purpose of emergency or immediate patient care, CSPs are exempted from the requirements described in this chapter for Low-Risk Level, Medium-Risk Level, and High-Risk Level CSPs when all of the following criteria are met:
  - USP 797

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- Immediate Use Exemption
- 1. Only simple aseptic measuring and transfer manipulations are performed with not more than three (3) sterile nonhazardous commercial drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution.
  - USP 797

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- Immediate Use Exemption
- 2. Unless required for the preparation, the preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.
  - USP 797
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Immediate Use Exemption
3. At no point during preparation and prior to administration are critical surfaces and ingredients of the CSP directly exposed to contact contamination such as human touch, cosmetic flakes or particulates, blood, human body substances (excretions and secretions e.g., nasal and oral), and nonsterile inanimate sources
USP 797

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Immediate Use Exemption
4. Administration begins not later than one (1) hour following the start of preparing the CSP.
Administration must be completed with 24 hours
USP 797

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Immediate Use Exemption
When the CSP is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the CSP shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond-use time and date. USP 797
Handling Sterile Pharmaceuticals

- Immediate Use Exemption
  - If administration has not begun within one (1) hour following the start of preparing the CSP, the CSP is promptly and safely discarded. Immediate Use CSPs shall not be stored for later use.
- USP 797

Questions on compounded sterile products?

Controlled substances

- Controlled Substances Act of 1970
- Enforced by Drug Enforcement Administration (DEA)
- Also enforced by state and local law enforcement, TDSHS, Texas State Board of Pharmacy, TJC, AAAHC, other.
- Don’t get burned.
- Great Emphasis—OC?
Controlled substances

- Has anyone had a visit from the DEA?
- Has anyone had narcotics stolen from their facility?
- Does anyone know someone in healthcare with a drug problem?
- Do you know someone who has lost a professional license?

Controlled substances

Requirements:
1. Biannual Inventory (every 2 years)
2. TSBP requires ANNUAL controlled substance inventory – R.Ph. Signature notarized. ***************
2. CII invoices with DEA 222 or e-222 (for CSOS [controlled substance ordering system]) maintained in separate file; completed and signed by person receiving drugs.
3. Power of Attorney to sign DEA 222.
Who can sign DEA 222?
Facility or personal 222s?
4. CIII-V invoices (signed) in separate file.
5. Controlled substance reproducible audit trail

POWER of Attorney

- **POWER OF ATTORNEY FOR DEA ORDER FORMS**

  - ________________ (Name of registrant)
  - ________________ (Address of registrant)
  - ________________ (DEA registration number)

  (Name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, executed, and acknowledged, and by these presents, do hereby vest in the attorney for me in my name, place, and stead, to execute applications for blank official order forms and to sign such order forms as required by Schedule I or controlled substances, in accordance with section 208 of the Controlled Substance Act (21 U.S.C. 828) and part 225 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

  - ________________ (Signature of person granting power)

  (Name of attorney-in-fact), hereby, refers to the person named herein as attorney-in-fact, and that the signature affixed hereto is my signature.

  - ________________ (Signature of attorney-in-fact)
  - ________________ (Address)

Signed and dated on the ______ day of ________, (year), at ________

POWER of Attorney

- **NOTICE OF REVOCATION**

  The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact ________ this same day.

  - ________________ (Signature of person revoking power)

  Witnesses: 1.
  - ________________
  2.
  - ________________

  Signed and dated on the ______ day of ________, (year), at ________

  http://www.mcbop.org/PDF/PowerOfAttorney.pdf
Controlled substances

- Reproducible Audit trail
  - A. Track all invoices for incoming controlled substances.
  - B. I recommend getting a monthly summary of all Controlled Substances received from wholesaler(s) and Validate it!
  - SH
- C. Valid documentation of administration

Controlled substances

- C. Valid documentation of Administration
- Texas Pharmacy Rules Require:
  - Date and time of administration, patient name, drug and dose administered, signature of person administering drug, amount of waste (if any), 2nd person signature witnessing wastage (if any)??, name of ordering practitioner.
  - Maintain separately from patient chart.
  - Where do you waste partial doses?

<table>
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<th></th>
<th>Date</th>
<th>Drug</th>
<th>Amount</th>
<th>Wasted</th>
<th>Administered by</th>
<th>Waste Witnessed by</th>
<th>Ordered by</th>
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</tbody>
</table>
### Controlled Substance Administration Record

**Date:** ___________  
**sheet #** _______________

**Start of day removal**

Signed out by:  

# Fent 2ml checked out
# Midaz 2mg checked out  
# Propofol 200mg/20ml Checked out to whom: _______________________

**Patient Sticker**  

Time of admin  

Fent dose:  

Midaz dose:  

Prop dose:  

Admin by (signature):  

Fent waste:  

Midaz waste:  

Prop waste:  

Waste witness (signature):  

End of day return  

# Fentanyl 2ml returned  
# returned  
# Midaz returned  
# Propofol returned

Return to stock witness by:  

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### Controlled substances

- D. Transfer of controlled substances to another registrant
- E. Documentation of Destruction by reverse management
- F. Documentation of theft and loss
- ! Complete Audit Trail—Everything in and everything out!

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### Controlled substances

- Reports of theft and loss
- Required to report “theft” or “significant loss”
- DEA 106 form is on-line

Why am I so familiar with these rules????
Controlled substances

6. “Adequate Security”
   - Double locked? Bolted to wall?
   - Security Camera? Armed guard?
   - Metal Cabinet? Steel Safe?
   - Bio ID?

   Two locks? Is this adequate security?

Summary for controlled substance tracking

A. Keep CII invoices and 222s separate and readily retrievable
B. Keep CIII-V invoices separate and readily retrievable.
C. Make sure all of the controlled substances received make it into your inventory!!
Controlled substances

- Ensure that you have a reproducible audit trail for all controlled substances – in and out.
- E. Adequate security
- F. Documentation of theft and loss
- G. Annual inventory

Who is usually the person who steals controlled substances?

The person you trust the most.

OTEC
Controlled substances

Questions on controlled substances?
Points of emphasis

- License
  - Name consistent
  - Address
  - Owners
  - Posted ORIGINAL
- MDV – as before
- Tracking purchased CSP
- Pharmacy contract

Controlled substances

Questions????????

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