Medication Management

Pharmacy News & Essentials for ASC Leaders
2024

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Confidential & Proprietary

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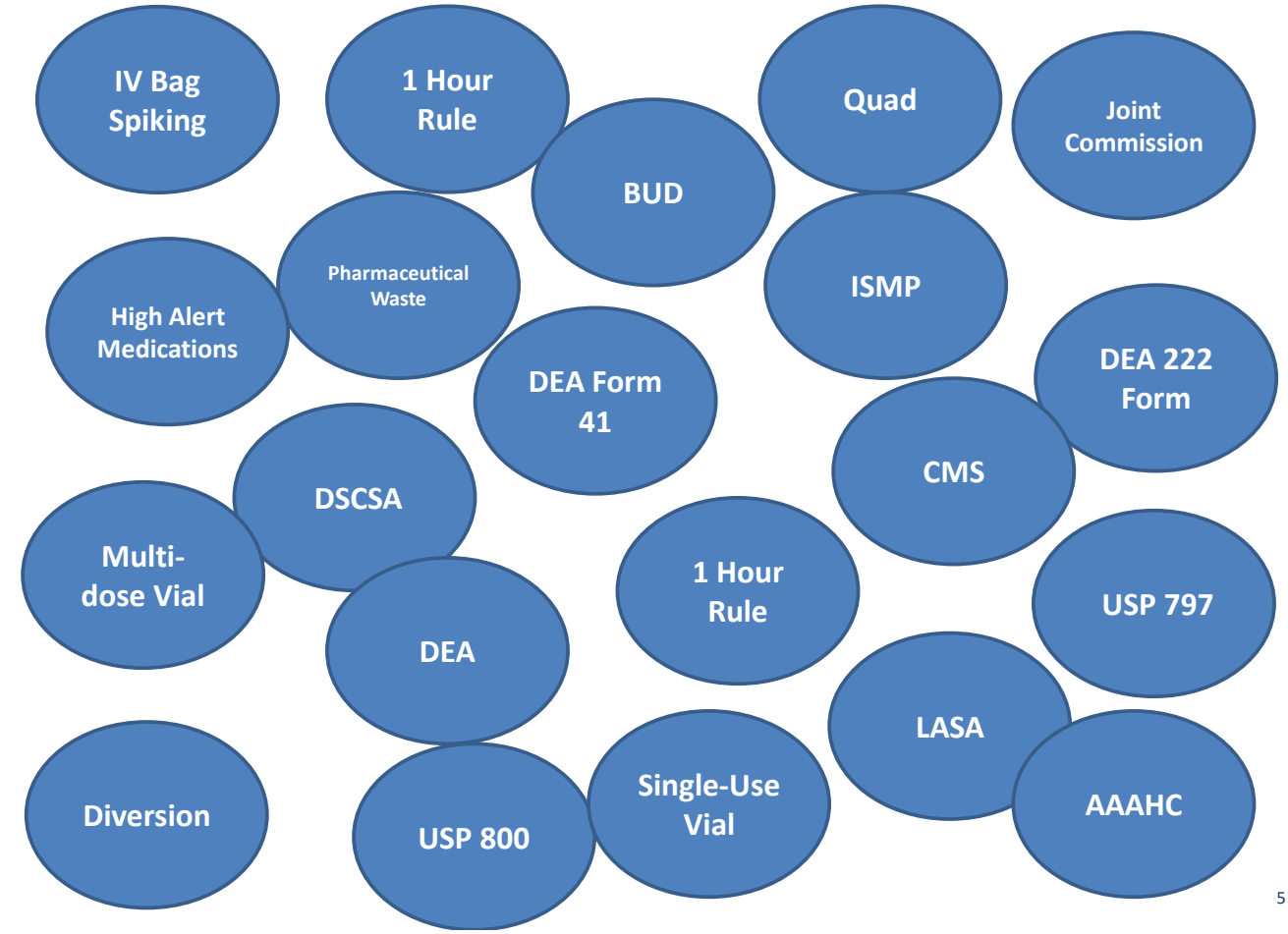
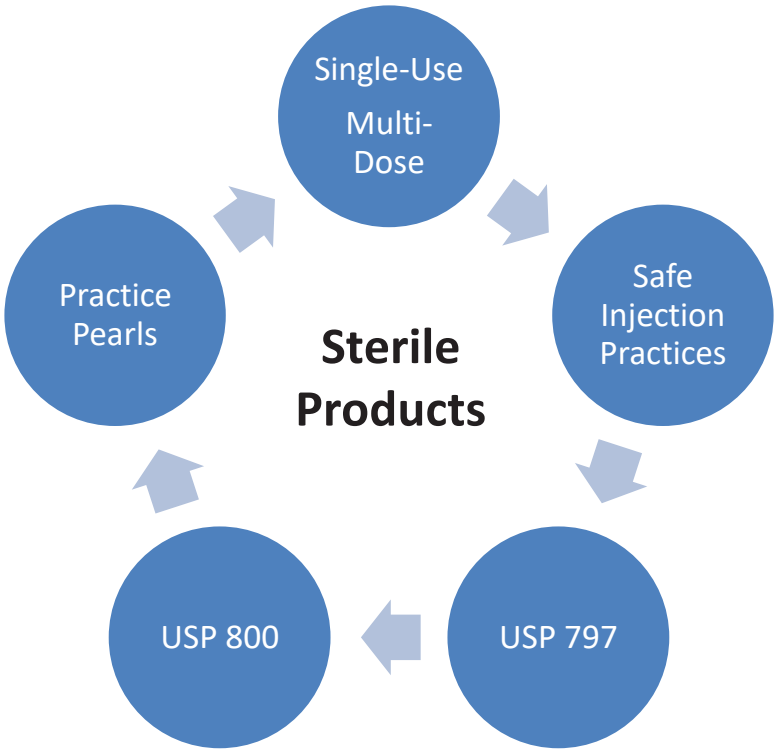
Learning Objectives

- Medication Management Updates - 2024
- Safety, Compliance and Best Practices
  - Accreditation, Regulations, Laws
- Highlights : Sterile products, USP 797/800, DEA, Emergency Management, Drug Shortages
- Practical, Informative, Interactive

Today's Topics



Sterile Products



Single-Use Vials

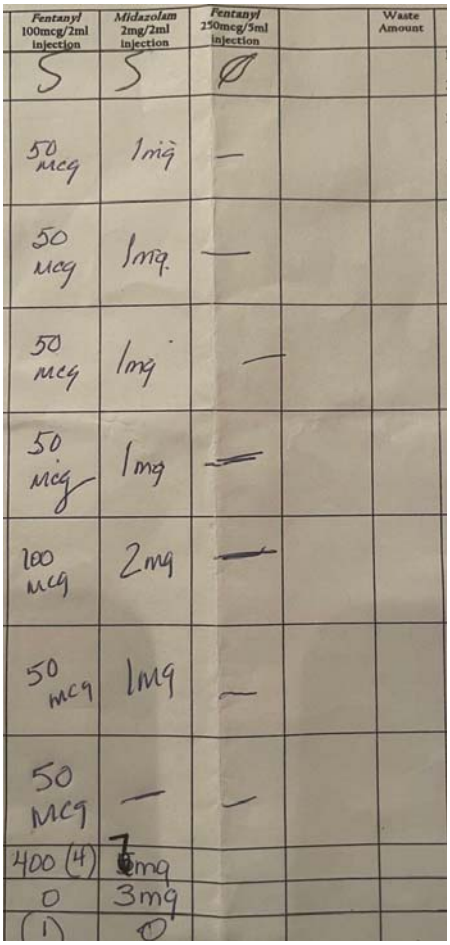
Single-Use Vials

- No Preservatives
- **Never** use on more than 1 patient
- Discard after use on single patient
- Includes common Anesthesia Meds (midazolam, fentanyl, morphine, etc.)

Multi-Dose Vials

Multi-Dose Vials

- Contains preservatives – no viral protection
- 28-day BUD outside of Procedural Areas
  - Aseptic Technique
  - Dated, Initialed
- ***Becomes Single-Dose when used within a patient treatment area*** (possible contamination)
- Waste it possible contamination!



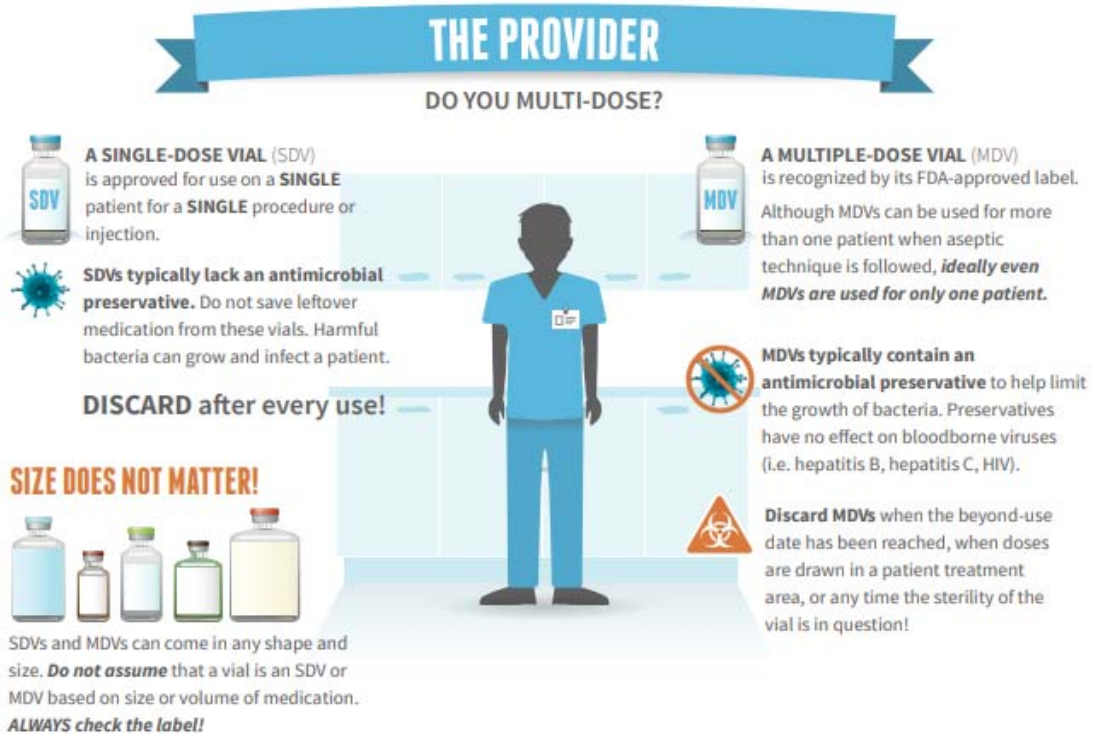
- Single-Use Vial
- Labeling / Storage
- Used in patient treatment area
- Anesthesia ‘through-put’
- Drug Shortage implications
- Cost implications
- CDC / FDA / USP 797

Most controlled substances are single-use

CDC's Position — Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials

The Centers for Disease Control and Prevention's guidelines call for medications labeled as "single-dose" or "single-use" to be used for only one patient. This practice protects patients from life-threatening infections that occur when medications get contaminated from unsafe use. Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to healthcare providers. CDC recognizes the problem of drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues unrelated to the above guidelines (http://www.fda.gov/DrugShortageReport). CDC 's priority is protecting patients from harm. CDC routinely investigates and is apprised of infectious disease outbreaks involving single-dose/single-use vials being used for multiple patients. These outbreaks cause extensive harm to patients, and they are associated with significant healthcare and legal expenses. Therefore, CDC continues to strongly support its current policies regarding single-dose/single-use vials. It is imperative that drug shortages and drug waste concerns are dealt with appropriately and do not lead to unsafe medical practices that impose increased disease risk on patients. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to subdivide contents of single-dose/single-use vials, as stated in United States Pharmacopeia General Chapter ‹797› Pharmaceutical Compounding – Sterile Preparations.

https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html



https://www.cdc.gov/injectionsafety/pdf/Injection-Safety-For-Healthcare-P.pdf

SAFETY STEPS

FOLLOW THESE INJECTION SAFETY STEPS FOR SUCCESS!

BEFORE THE PROCEDURE

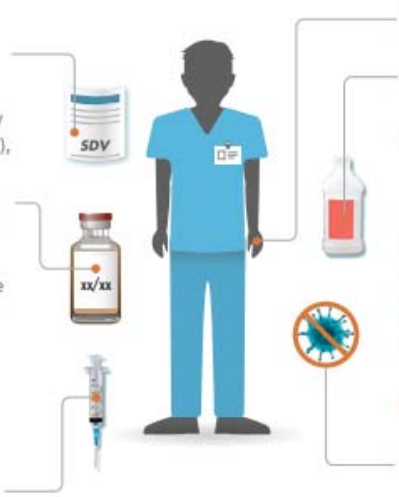
Carefully ***read the label*** of the vial of medication.

- If it says single-dose and it has already been accessed (e.g. needle-punctured), ***throw it away.***
- If it says multiple-dose, ***double-check the expiration date*** and the beyond-use date if it was previously opened, and visually inspect to ensure no visible contamination.
- When in doubt, throw it out.

DURING THE PROCEDURE

Use aseptic technique.

- Use a new needle and syringe for every injection.



- Be sure to clean your hands immediately before handling any medication.
- Disinfect the medication vial by rubbing the diaphragm with alcohol.
- Draw up all medications in a clean medication preparation area.

AFTER THE PROCEDURE

Discard all used needles and syringes and SDVs after the procedure is over.

MDVs should be discarded when:

- the beyond-use date has been reached
- doses are drawn in a patient treatment area
- any time vial sterility is in question

www.cdc.gov/injectionsafety/1anonly.html

https://www.cdc.gov/injectionsafety/pdf/Injection-Safety-For-Healthcare-P.pdf

INJECTION SAFETY CHECKLIST

The following Injection Safety checklist items are a subset of items that can be found in the *CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care.*

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare providers to safe injection practices. Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.

Injection Safety	Practice Performed?	If answer is No, document plan for remediation
Proper hand hygiene, using alcohol-based hand rub or soap and water, is performed prior to preparing and administering medications.	Yes No	
Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment.	Yes No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	Yes No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	Yes No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	Yes No	
Single-dose or single-use medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	Yes No	
Medication administration tubing and connectors are used for only one patient.	Yes No	
Multi-dose vials are dated by healthcare when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date printed on the vial.	Yes No	
Multi-dose vials are dedicated to individual patients whenever possible.	Yes No	
Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). Note: If multi-dose vials enter the immediate patient treatment area, they should be dedicated for single-patient use and discarded immediately after use.	Yes No	

https://www.cdc.gov/injectionsafety/PDF/Safe-Injection-Checklist-P.pdf

STERILE PRODUCTS

What is 'USP'?

- **United States Pharmacopeia (USP)**
  - Established in 1820
  - Non-Profit / Non-governmental
  - Mission to "improve global health through public standards and related programs that help ensure QUALITY, SAFETY and BENEFIT of medications and foods"
  - Gold Standard for sterile and non-standard Pharmaceutical Compounding
  - USP 797 / USP 800 – Most applicable to ASCs
  - 797 Revisions finalized after delay on **11/1/22**
    - 1-year implementation period

www.usp.org

Resources

- USP <797> FAQs
- USP <797> Commentary
- USP General Chapter Education Courses
- Sign up for USP Healthcare Quality & Safety Updates

USP 797 Updates
November 1, 2022

⟨797⟩ Revisions

Immediate-Use CSPs

Requirements for Immediate-Use CSPs
Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
The preparation involves not more than 3 different sterile products.
Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-hour time period within which administration must begin.

20

What is a ‘sterile product’ according to USP 797?

Pharmaceutical Compounding – Sterile Preparations

REVISIONS TO <797> | OFFICIAL STATUS NOTIFICATION | ACCESS <797> VIA COMPOUNDING COMPENDIUM

SIGN UP FOR COMPOUNDING UPDATES

Millions of medications are compounded each year in the US to meet the unique needs of patients. Compounding provides access to medication for patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases. Medications that are required to be sterile include those administered through injection, intravenous infusion (IV), intraocular (injection in the eye) or intrathecal (injection in the spine).

Understanding the risks inherent in sterile compounding and incorporating established standards are essential for patient safety. Compounded medications made without the guidance of standards may be sub-potent, super potent or contaminated, exposing patients to significant risk of adverse events or even death.

USP develops standards for preparing compounded sterile medications to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing.

3. What is the definition of sterile compounding?

For purposes of General Chapter <797>, sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile medication. However, administration and preparation per the manufacturer's approved labeling are out of the scope of the chapter as described in *1.2 Administration* and *1.4 Preparation Per Approved Labeling*, respectively.

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USP 797 / 800
Administration is now ‘out of scope’

17. Is administration out of the scope of the chapter?

Yes. The intent of the chapter is to establish minimum standards for practitioners when compounding sterile products in order to minimize harm, including death, to human and animal patients. The scope of the chapter is intended to ensure a CSP maintains its integrity up until the time when administration begins. Standard precautions such as the Centers for Disease Control and Prevention's (CDC's) safe injection practices apply to administration (see *1.2 Administration*).

20. Is withdrawing a dose from a container of a conventionally manufactured sterile product or spiking an IV bag, without any further manipulation, for immediate administration to a patient considered compounding?

No, withdrawing a dose from a container or spiking an IV bag of a conventionally manufactured sterile product without any further manipulation is considered administration rather than compounding and is out of the scope of <797>. If the dose is further mixed with another product, it would be considered compounding and subject to the requirements of <797>.

21. Is spiking IV fluids (taking IV spikes and putting them into a bag; putting a set into an IV bag) considered compounding?

No, a facility's policies and procedures regarding spiking IV fluids is outside the scope of the chapter.

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Who does USP 797 / USP 800 apply to?

4. To whom do the standards in General Chapter <797> apply?

This chapter applies to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared for human and animal patients. This includes, but is not limited to, pharmacists, technicians, nurses, physicians, veterinarians, dentists, naturopaths, and chiropractors in all places including, but not limited to, hospitals and other healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' or veterinarian practice sites. Any person entering a sterile compounding area, whether preparing a CSP or not, must meet the requirements in *3. Personal Hygiene and Garbing.*

Please note, compounding of sterile hazardous drugs (HDs) must additionally comply with General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings.*

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It is *NOT* Compounding if…….

USP 797 – Section 1.3

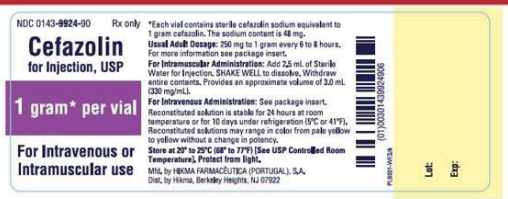
- **Aseptic technique** is used
- Processes are in place to **minimize contact w/ non-sterile surfaces, introduction of particulate matter/body fluids, and no mix-ups w/ other products or CSPs**
- **Physical & chemical compatibility** are evidence-based & confirmed
- The preparation involves **not more than 3 different sterile products**
- Unused, **single-use drugs** involved are discarded after preparation and **NEVER used on more than 1 patient**
- **Must be labeled** if administered by someone other than the preparer or preparer does not witness administration
  - 1) Drug names including diluent 2) Initials of preparer 3) 4-hour BUD

……it is also *NOT* compounding, when……

(USP 797 – Section 1.4)

Compounding ***does not*** include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided **(the Package Insert)** by the manufacturer and other directions from the manufacturer (supplemental information from manufacturer).

1. **The product is prepared for a single dose for an individual patient.**
2. **The package insert includes information for:**
    1. **Correct diluent to use**
    2. **Final strength/concentration of the product**
    3. **Container closure system (bag, syringe, etc.)**
    4. **Storage time**



https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1dc9de56-e259-4546-a1db-23119a8a088e&type=display

RECONSTITUTION

Preparation of Parenteral Solution

Parenteral drug products should be SHAKEN WELL when reconstituted, and inspected visually for particulate matter prior to administration. If particulate matter is evident in reconstituted fluids, the drug solutions should be discarded.

When reconstituted or diluted according to the instructions below, Cefazolin for Injection is stable for 24 hours at room temperature or for 10 days if stored under refrigeration (5°C or 41°F). Reconstituted solutions may range in color from pale yellow to yellow without a change in potency.

Single-Dose Vials

For IM injection, IV direct (bolus) injection or IV infusion, reconstitute with Sterile Water for Injection according to the following table. SHAKE WELL.

Vial Size	Amount of Diluent	Approximate Concentration	Approximate Available Volume
500 mg	2 mL	225 mg/mL	2.2 mL
1 gram	2.5 mL	330 mg/mL	3 mL

ADMINISTRATION

Intramuscular Administration

Reconstitute vials with Sterile Water for Injection according to the dilution table above. Shake well until dissolved. Cefazolin for Injection should be injected into a large muscle mass. Pain on injection is infrequent with Cefazolin for Injection.

Intravenous Administration

Direct (bolus) injection: Following reconstitution according to the above table, further dilute vials with approximately 5 mL Sterile Water for Injection. Inject the solution slowly over 3 to 5 minutes, directly or through tubing for patients receiving parenteral fluids (see list below).

Intermittent or continuous infusion: Dilute reconstituted Cefazolin for Injection in 50 to 100 mL of 1 of the following solutions:

- Sodium Chloride Injection, USP
- 5% or 10% Dextrose Injection, USP
- 5% Dextrose in Lactated Ringer's Injection, USP
- 5% Dextrose and 0.9% Sodium Chloride Injection, USP
- 5% Dextrose and 0.45% Sodium Chloride Injection, USP
- 5% Dextrose and 0.2% Sodium Chloride Injection, USP
- Lactated Ringer's Injection, USP
- Invert Sugar 5% or 10% in Sterile Water for Injection
- Ringer's Injection, USP
- 5% Sodium Bicarbonate Injection, USP

So what is 'in scope'?

- Repackaging of all Sterile Products

16. Does the chapter apply for repackaging of a conventionally manufactured sterile product?

Yes, repackaging of a sterile product or preparation from its original container into another container must be performed in accordance with the requirements in this chapter.

- Preparation of more than 3 different sterile products

22. When compounding immediate-use CSPs, may more than three individual containers of a sterile product be used?

The immediate-use CSPs provision states that the preparation must not involve more than 3 different sterile products. Two or more of the same sterile components (product) may be used as long as there are not more than three different sterile components (products). For example, two vials of the same component (drug product) are reconstituted using two vials of *Sterile Water for Injection* (component products) and added to a single component product intravenous diluent bag such as NS or D5W. As another example, when the CSP requires combining 4 vials of the same component (drug product) into a single component product intravenous bag of diluent, only 2 different sterile components (products) are used to prepare the CSP. Both examples may be considered immediate- use as long as the criteria listed in *1.3 Immediate-Use CSPs* are met.

- Any deviation from the Package Insert

26. Is it considered compounding if the steps used to prepare a single dose of a conventionally manufactured product are different from the directions contained in the manufacturer's approved labeling?

Yes. Any compounding (e.g., mixing, reconstituting) that is not performed according to the manufacturer's approved labeling is considered sterile compounding and is subject to the requirements in the chapter.

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Naropin®

(ropivacaine HCl) Injection

Rx only

DESCRIPTION:

Naropin® Injection contains ropivacaine HCl which is a member of the amino amide class of local anesthetics. Naropin Injection is a sterile, isotonic solution that contains the enantiomerically pure drug substance, sodium chloride for isotonicity and water for injection. Sodium hydroxide and/or hydrochloric acid may be used for pH adjustment. It is administered parenterally.

Ropivacaine HCl is chemically described as S-(-)-1-propyl-2',6'-pipecoloxylidide hydrochloride monohydrate. The drug substance is a white crystalline powder, with the following structural formula:

At 25°C ropivacaine HCl has a solubility of 53.8 mg/mL in water, a distribution ratio between n-octanol and phosphate buffer at pH 7.4 of 14:1 and a pKa of 8.07 in 0.1 M KCl solution. The pKa of ropivacaine is approximately the same as bupivacaine (8.1) and is similar to that of mepivacaine (7.7). However, ropivacaine has an intermediate degree of lipid solubility compared to bupivacaine and mepivacaine.

Naropin Injection is preservative-free and is available in single dose containers in 2 (0.2%), 5 (0.5%), 7.5 (0.75%) and 10 mg/mL (1%) concentrations. The specific gravity of Naropin Injection solutions range from 1.002 to 1.005 at 25°C.

Solutions should be stored at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

The container closure is not made with natural rubber latex.

These products are intended for single dose and are free from preservatives. Any solution remaining from an opened container should be discarded promptly. In addition, continuous infusion bottles should not be left in place for more than 24 hours.

NAROPIN is a trademark of Fresenius Kabi USA, LLC.

USP 797 / Single-Use

Immediate Jeopardy

24. Can a single-dose container be used to prepare doses for more than one patient when compounding an immediate-use CSP?

No. One of the conditions of the immediate-use CSP provision specifies that any unused starting components from a single-dose container must be discarded after preparation for the individual patient is complete. Single-dose containers must not be used for more than 1 patient when used for preparing immediate-use CSPs.

30. What is the difference between compounding and what is described in *1.4 Preparation Per Approved Labeling*?

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer if the product is prepared as a single dose for an individual patient and the approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time.

Patient MR Number	KETAMINE 1 x 5ml Total 5 ml	FENTANYL 4 x 2ml Total 8 ml	SUFENTANIL 4 x 1ml, ∅ x 2ml Total 2 ml	ALFENTANIL 4 x 2ml Total 8 ml	MIDAZOLAM 2mg/2ml 4 x 2ml Total 8 ml	MORPHINE 10mg 1 x 1ml Total 1 ml	DILAUDID 1mg/ml 1 x 1ml Total 1 ml
Added:	____ ml	____ ml	____ ml	____ ml	____ ml	____ ml	____ ml
Total For Day:	5 ml	2 ml	2 ml	8 ml	8 ml	1 ml	1 ml
69119			15mcg				
69313		1ml					
69339			15mcg				
29818			20mcg				
68476			10mcg				
68904		1ml	20mcg				

Best Practice or Bad Practice?

1-Hour → 4-Hour Rule

NEW

25. Why does the immediate-use CSP provision allow for administration to begin within 4 hours following the start of the preparation?

The immediate-use CSP provision was revised to allow up to 4 hours for beginning administration to balance the need for ensuring CSP quality with timely access to medication in a variety of healthcare settings. The allowance of up to 4 hours was based on the 4-to-6-hour lag phase of microbial growth, during which potential bacterial cells are adjusting to their environment and change very little, and they do not immediately start reproducing.[1] In the event bacterial cells were inadvertently introduced into a CSP during compounding, replication is unlikely and therefore there is a window of time in which a CSP can be held prior to administration.

[1] References:

- Daquigan N et al. Early recovery of *Salmonella* from food using a 6-hour non-selective pre-enrichment and reformulation of tetrathionate broth. *Front Microbiol*. 2016;7:2103.
- Jarvis, Basil. *Statistical Aspects of the Microbiological Examination of Foods, Third Edition*. Academic Press, 2016.
- Ryan, Kenneth et al. *Sherris Medical Microbiology, Sixth Edition*. McGraw-Hill Education, 2014.
- Wang J et al. A novel approach to predict the growth of *Staphylococcus aureus* on rice cake. *Front Microbiol*. 2017;8:1140.

38. Do facilities have to change their standard operating procedures (SOPs) and practices for immediate-use from 1 h to 4 h?

No, facilities may choose to maintain the 1-hour limit for administration of immediate-use CSPs, however increasing the time to 4 hours would be considered acceptable.

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4-Hour Rule Exceptions

- If the PI states otherwise

18. Does a conventionally manufactured sterile product prepared for administration to a single patient in accordance with manufacturer's approved labeling outside of ISO Class 5 conditions have to be administered within 4 hours of reconstitution or mixing if it meets all the conditions in *1.4 Preparation Per Approved Labeling*?

No. When all of the conditions in *1.4 Preparation Per Approved Labeling* are met, the storage information in the manufacturer's approved labeling may be followed.

- If center chooses to stay with 1-Hour rule

38. Do facilities have to change their standard operating procedures (SOPs) and practices for immediate-use from 1 h to 4 h?

No, facilities may choose to maintain the 1-hour limit for administration of immediate-use CSPs, however increasing the time to 4 hours would be considered acceptable.

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Sterile Products 'Designated 'Person'

10. Who can be the designated person(s)?

The designated person is one or more individuals assigned by the facility to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded sterile preparations (CSPs). Facilities must determine whether they have one or more designated person(s), select the designated person(s), and determine how to allocate responsibility if there is more than one designated person. The designated person(s) can delegate activities to an assigned trainer provided that is described in the organization's policies.

32. What qualifications must a designated person have?

This must be determined by the facility's SOPs. Some states and accreditation organizations have more specific guidance.

- One or more individuals – designate specific responsibilities if more than one
- Responsible and accountable for compounded sterile products (CSP) in facility
- Write in SOPs

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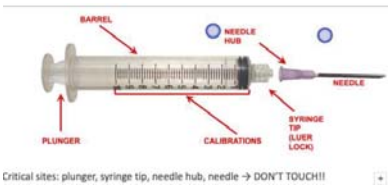
Competencies now required

41. What are the training and competency assessment requirements for personnel who only prepare immediate-use CSPs?

Training and competency assessment requirements are determined by the specific tasks performed and the facility's SOPs, and must include aseptic processes to minimize the potential for contact with nonsterile surface surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.

42. How often does the training and competency of personnel who perform immediate-use products need to be performed?

Section *1.3 Immediate-Use CSPs* requires that personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. No specific frequency is identified for training and competency of personnel who perform compounding of immediate-use CSPs.



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https://ashpadvantage.com/expert-insight/dos-and-donts-of-usp-chapter-797-personnel-training/

INJECTION SAFETY CHECKLIST

The following Injection Safety checklist items are a subset of items that can be found in the *CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care.*

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare providers to safe injection practices. Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.

Injection Safety	Practice Performed?	If answer is No, document plan for remediation
Proper hand hygiene, using alcohol-based hand rub or soap and water, is performed prior to preparing and administering medications.	Yes No	
Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment.	Yes No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	Yes No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	Yes No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	Yes No	
Single-dose or single-use medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	Yes No	
Medication administration tubing and connectors are used for only one patient.	Yes No	
Multi-dose vials are dated by healthcare when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date printed on the vial.	Yes No	
Multi-dose vials are dedicated to individual patients whenever possible.	Yes No	
Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). Note: If multi-dose vials enter the immediate patient treatment area, they should be dedicated for single-patient use and discarded immediately after use.	Yes No	

https://www.cdc.gov/injectionsafety/PDF/Safe-Injection-Checklist-P.pdf

New Ophthalmic Product Process
No more 28 day BUD

179. Are conventionally manufactured sterile topical ophthalmic products considered multiple-dose containers?

No, <659> *Packaging and Storage Requirements* defines multiple-dose containers as a container closure system that holds a sterile medication for parenteral administration (injection or infusion) that has met antimicrobial effectiveness testing requirements, or is excluded from such testing requirements by FDA regulation. Therefore, the requirement that multiple-dose containers not be used for more than 28 days unless otherwise specified on the labeling does not apply to conventionally manufactured sterile topical products.

- Eye drops and ointments may be used through the manufacturer's expiration date after being opened.
- If contamination is suspected, immediately discard. If the product is designated 'Single-Use' by the FDA, it can only be used on 1 patient.
- Always follow the **Package Insert** for BUD guidance.

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USP 797 Update FAQs

43. Is the use of dispensing pins allowed per <797>?

The chapter does not address the use of specific disposable supply items other than to say supplies in direct contact with the CSP must be sterile and depyrogenated. It is the responsibility of the facility to determine the appropriateness of specific items, including dispensing pins.

file:///C:/Users/User/Downloads/USP22_HQS_Compounding_797_FAQ_Document_V2a.pdf

USP 797 Immediate-Use Summary

- Compounding involves no more than 3 different sterile products
- If more than 3 products, must be compounded is ISO environment (compounding pharmacy)
- Aseptic Technique : Clean surface / Clean hands/ Alcohol swab & dry
- **1-hour to 4-hour rule - refer to package insert**
- Label if not administered or witnessed by the preparer
- Label must include name of drug/diluent, Initials of preparer, BUD time
- Avoid pre-drawing doses when possible

USP 800

(in accordance with USP 797)

Hazardous Drug Handling

https://www.prsrx.com/usp800track/

What are Hazardous Drugs?

- Carcinogenic
- Developmental Toxicity (including teratogenicity)
- Reproductive toxicity
- Genotoxic
- Organ toxicity at low doses

USP 800

KNOW YOUR EXPOSURE TO HAZARDOUS DRUGS

Help minimize your risk with the USP <800> HazRx® mobile app

What is the exposure?

usp.org

More than **8 million**

U.S. healthcare workers are exposed to hazardous drugs every year[1]

More than **12 billion**

doses of hazardous drugs are handled

Drugs are classified as **hazardous** when they possess any of **these characteristics**[1]:

- Impact or damage DNA/genes
- Cause cancer
- Contribute to infertility
- Impact a developing embryo or fetus
- Cause developmental abnormalities
- Cause organ damage
- Have a similar structure or function to drugs that are determined to

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

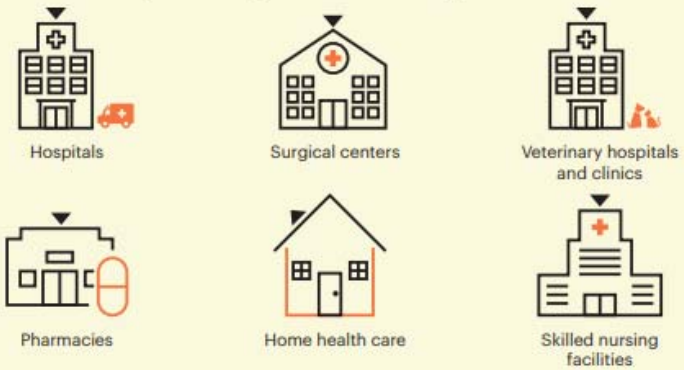
Who is at risk?

Anyone handling hazardous drugs is at risk of exposure[1]

- Pharmacists
- Pharmacy Technicians
- Nurses
- Physicians
- Surgeons
- Physician Assistants
- Respiratory Therapists
- Home Health Aides
- Nurses' Aides
- Housekeeping
- Janitorial Services
- Environmental Services
- Veterinarians
- Veterinarian Technicians
- Veterinarian Assistants

Where can exposure occur?

Exposure can take place in any healthcare setting[1,6]



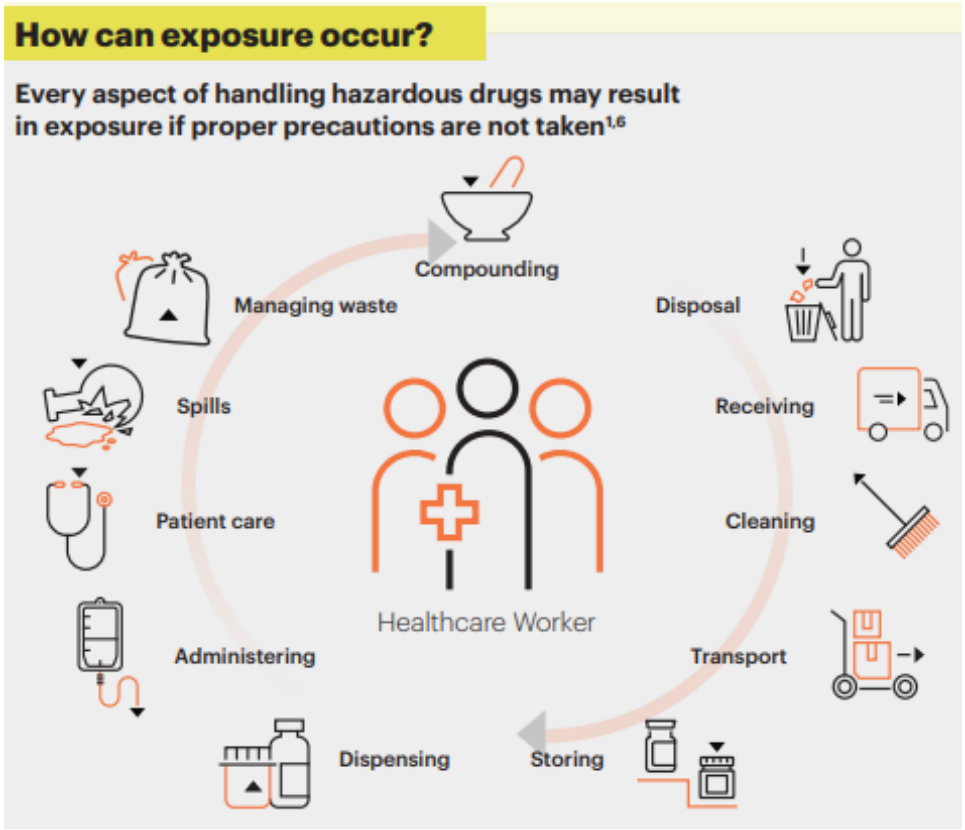
USP 800

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

USP 800

https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

USP 800



https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

1) Identify 'Point' Person to Oversee

2) Assessments / Build Plan

3) Develop center Hazardous Drug List

4) Assessments of Risk (AOR)

5) Implement

USP 800

5 Steps to Success

1) Identify 'Point' Person

Understanding of USP 800

Work with Consultant Pharmacist

Risks to Staff / Policy Plan

Risks of Non-Compliance

Assessing Compliance Risks

Policies / SOPs

Work with Staff to develop

Overall Compliance Plan

Employee Competencies

Annual Risk Assessments

Day to Day Oversight

2) Assessments

Exposure Risks / Processes : Receiving, Storage, Use, Disposal

Personnel Assessment

Who is exposed? How often exposed?

Safe Work Practices/Processes

Proper Use of PPE

Preparation/Administration/ Disposal

Policies / SOPs

3) Develop Haz Drug List

2016 CDC NIOSH List

Not EPA or OSHA List

NIOSH Hazardous Drug List / Formulary Cross Reference

Formulary Deletions if possible

Examples in each NIOSH Table

Table 1	• **Mitomycin (Mitosol™)** • Hydroxyurea • Megestrol • Methotrexate • Tamoxifen
Table 2	• Estradiol – Estrace™ • Carbamazepine – Tegretol™ • Phenytoin - Dilantin™ • Spironolactone
Table 3	• Oxytocin – Pitocin™ • Testosterone • Warfarin – Coumadin™

4) Create Assessment of Risks

Drug/Risk Group/Dose Form/Exposure Risk/Packaging/PPE

Inform Staff of Drugs/Risks

Review Annually
(during Formulary review)
Staff Competencies /Acknowledgement

Drug Name / Strength
Hazardous Group Packaging
Dose Form
Risk of Exposure
Storage
PPE

Documentation

5) Implementation

PPE Assessment

Gloves, Gowns, Disposal

Label

HD storage / Receiving & Storage Areas

Staff Competency

Storage and Use

Label as Hazardous Drug

Closed-System Transfer Devices (CSTD)

When applicable

Spill Kits

Waste bins

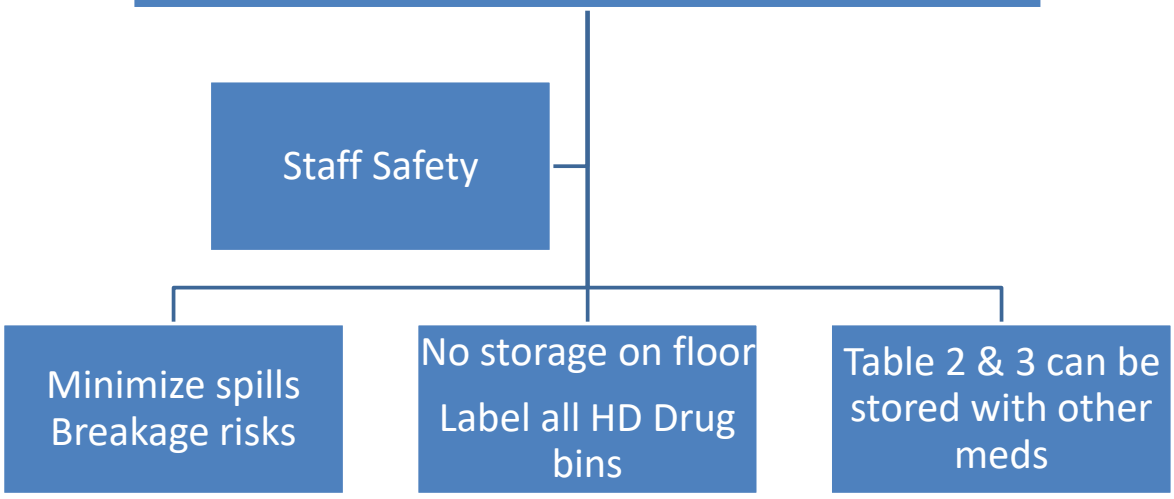
Assessment of Risk Example

USP 800 ASSESSMENTS OF RISK

Drug	Hazardous Grouping	Packaging	Form	Risk of Exposure	Storage	Single -Double Glove	Chemo Gown	Eye Protection	N-95
Bevacizumab (Avastin)	Group 1 / Antineoplastic	Prep from 503B Pharmacy	Syringe	Reproductive / Teratogenic	Individual bin / Leave in packaging from pharmacy until ready for use	Double	Yes	Yes if risk to eye exposure	No
Cytotec (misoprostol)	Group 3 / Reproductive	Bottle	Tablet	Fertility / Fetal	Bottle until dispense	Single	No	No	No
Estrace Cream	Group 2 / Non-Antineoplastic	Tube	Topical	Reproductive risk - Black Box warning - Cardivascular risk,	Indivudal bin	Single	No	No	No
Methylergonovine injection	Group 3 / Reproductive	Vial/Amp	Inject	Uterotonic effects	Individual bin	Single	No	No	No
Mitomycin Ophthalmic	Group 1 / Antineoplastic	Prep from 503B Pharmacy	Syringe	Mutagenic risk / Cancer	Individual bin / Leave in packaging from pharmacy until ready for use	Double	Yes	Yes if risk to eye exposure	No
Oxytocin Injection	Group 2 / Non-Antineoplastic	Unit of Use - Vial	Injection	Reproductive risk for women - potential spontaneous labor	Individual bin	Single	No	Yes if risk to eye exposure	No
Phenytoin Injection	Group 2 / Non-Antineoplastic	Unit of Use - Vial	Injection	Fertility risk	Individual bin				
Premarin Cream	Group 2 / Non-Antineoplastic	Tube	Topical	Reproductive risk - Black Box warning - Cardivascular risk,	Indivudal bin	Single	No	No	No

- Reviewed Annually as part of Formulary Review
- Imbed into Annual Competency Process
- Inform Staff of all exposure risks
- Staff acknowledgement
- Documentation

Hazardous Drug Storage



PPE Suggestions for Hazardous Drugs:

Receiving / Preparing / Handling / Administration / Spill Cleaning

Single Gloves: Table 2 Drugs	**Double Gloves:** Table 1 Drugs & Table 2 Drugs for contaminated Body fluids / Spills / Cleaning	**Chemo Gown:** Table 1 Drugs & Table 2 Drugs for contaminated Body fluids / Spills / Cleaning	**Eye Protection:** Table 1 &2 Drugs if potential for exposure	**Respiratory Protection:** Table 1 &2 Drugs if potential for exposure

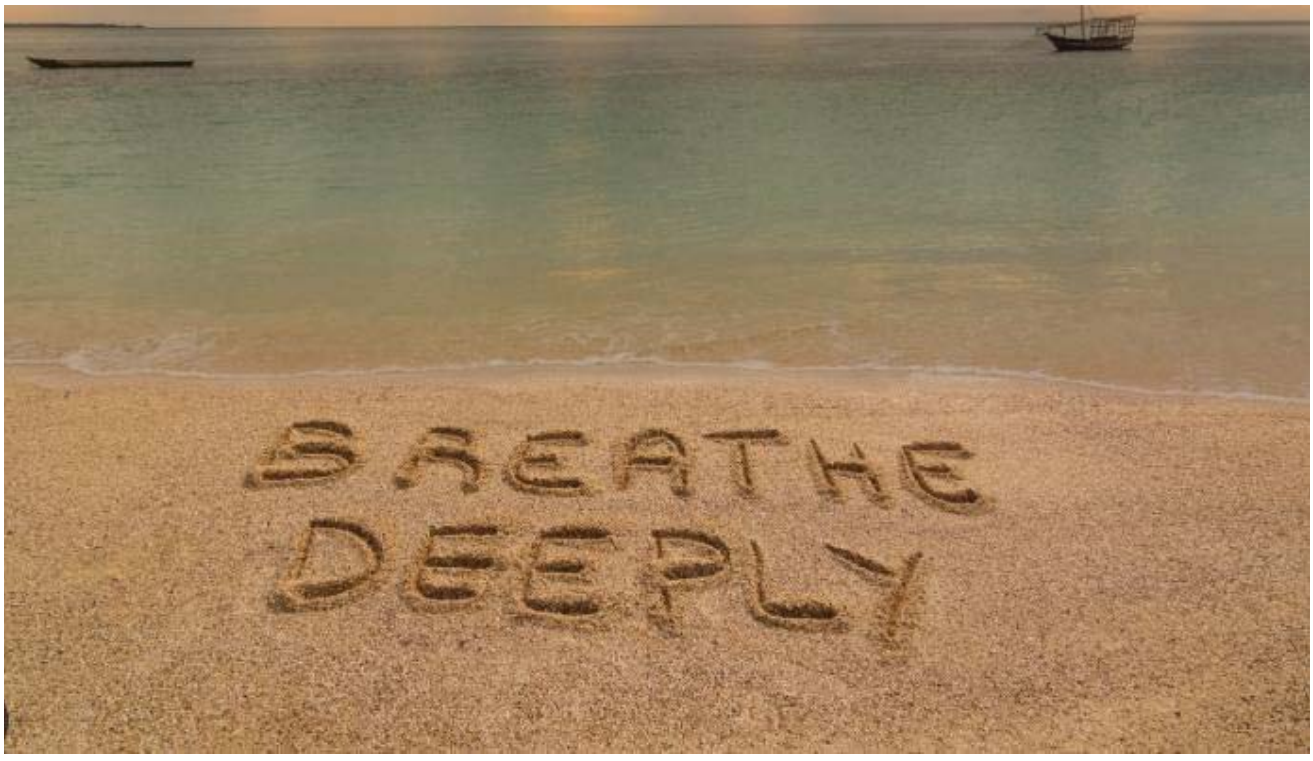
Work with your Consultant Pharmacist

Hazardous Drug -- ASC Impact

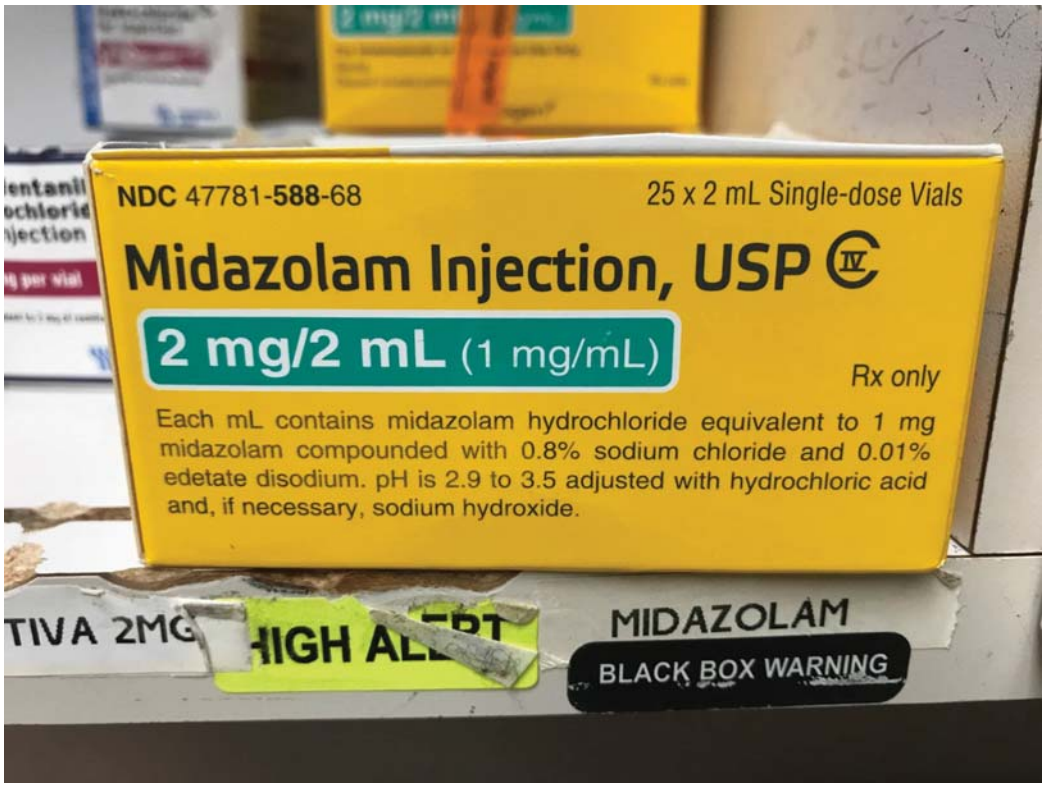
- All Table 1 Meds ***compounded by a Qualified Pharmacy***
  Table 1 drugs should not be stored in ASC prior to compounding * Final Finished Form assessment
- Table 2 /3 Meds – Not many used in ASC / Perform AOR / Educate & Inform / Label
- Assess Receiving/Storing processes. PPE availability, Waste containers, Spill Kit and process

Best Practice or Bad Practice?

Best Practice or Bad Practice?



Controlled Substances in the ASC



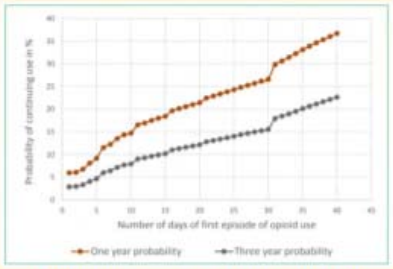
Controlled Substance Management

Why are prescription limits a solution to the opioid crisis?

More and more studies confirm that initial duration and dosage matter in determining an individual's likelihood of being on opioids long-term. By setting appropriate limits on initial opioid prescriptions while maintaining individualized pain management care, Tennessee encourages prevention of long-term opioid use and abuse.

Risk of Addiction and Abuse Grows with Duration and Dosage

The likelihood of continuing to use opioids increases most dramatically after the 5th and 31st days on therapy; the filling of the second prescription of opioids; a 700 MME cumulative dose of opioids; and first prescriptions with 10- and 30-day supplies. (CDC, 2017)



One- and three-year probabilities of continued opioid use, by duration of first episode in days.

Each refill and week of opioid prescriptions is associated with a large increase in opioid misuse among opioid naive patients. Duration of the prescription rather than dosage is more strongly associated with ultimate misuse in the early postsurgical period. (BMJ, 2018)

Treatment with opioids is not superior to treatment with non-opioid medications in improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain. (JAMA, 2018)

New persistent opioid use can be considered one of the most common complications after elective surgery and is more common than previously reported. (JAMA Surgery, 2017)

www.tntogether.com

https://www.tn.gov/tnfacesofopioids.html

Controlled Substance

Best Practices

- Closed-loop processes / Count sheets mirror cabinet order
- Clear/Concise documentation / Initial changes
- 2 licensed staff involved in each process
- Secure at ***ALL*** times
- Discovery / Disciplinary processes
- Third-Party verification / review (Pharmacist)
- Cameras over narcotic cabinet / Med Room

Controlled Substances

Best Practices

- Annual assessment of controlled substance use at your ASC
- Knowledge of State Laws / Prescriber Law / E-Prescribing
- Prescribing from ASC versus Office-based
- Controlled Substance Monitoring Database (CSMD)
- Accrediting Body Guidance of Opioid Management (TJC)
- E-Prescribing Laws – Code of Federal Regulation (CFR)
- Controlled Substance Monitoring Database (CSMD)

Controlled Substances

Inventory /Documentation

- Initial Inventory with each change to DEA license
- New DEA license? Transfer all controlled substances
- Ongoing inventory at least every 2 years – 'Biennial'
- Separate Inventory for CII v CII-CV
- Keep CII documentation separate from CIII - CV
- DEA 222 (C-IIs) & official invoice (C-III – C-V) transfers
- DEA Field Office for your Area/Region – Interpretation

Documentation Binders
Suggestion

1. **DEA 222 Forms**
    1. DEA License
    2. Unused DEA 222 forms with Log
    3. Power of Attorneys (POAs)
    4. Completed DEA 106 Forms
2. **CII Documentation (chronological)**
    1. CII Biennial Inventory
    2. Completed/Voided DEA 222 Forms
    3. Completed DEA 41 Forms
    4. Invoices (signed & dated by 2 people)
    5. Transfer DEA 222 Forms (to other Registrants)
3. **CIII – CV Documentation (chronological)**
    1. CIII – CV Biennial Inventory
    2. Invoices (signed & dated by 2 people)
    3. Completed DEA 41 Forms
    4. Transfer Forms (to other Registrants)

DEA 222 Log
Example

DEA FORM 222 INVENTORY LOG

DEA FORM 222 INVENTORY #	PERSON COMPLETING FORM	DATE ORDERED	CONTROLLED SUBSTANCE ORDERED	VENDOR	DATE MAILED	DATE RECEIVED
		03/06/14	FENTANYL/VERSED	PPC	N/A	03/06/14
		09/29/14	FENTANYL	McKESSON	09/29/14	10/07/14
		VOID	VOID	VOID	VOID	VOID
		03/12/15	FENTANYL	McKESSON	03/13/15	03/25/15
		05/18/15	FENTANYL	McKESSON	05/19/15	05/27/15
		08/17/15	FENTANYL	McKESSON	08/19/15	DEA 222 REJECTED/RETURNED
		09/04/15	FENTANYL	McKESSON	09/04/15	09/09/15
		10/30/15	FENTANYL	McKESSON	10/30/15	11/5/15
		1/20/16	FENTANYL	McKESSON	01/20/16	01/28/16
		03/01/16	FENTANYL	McKESSON	03/01/16	03/08/16
		05/31/16	FENTANYL	McKESSON	05/31/16	06/07/16
		07/18/16	FENTANYL	McKESSON	07/18/16	7/22/16
		08/16/16	FENTANYL	McKESSON	08/17/16	08/24/16
		10/17/16	FENTANYL	McKESSON	10/18/16	10/26/16
		12/7/16	FENTANYL	McKESSON	12/07/16	12/14/16
		02/23/17	FENTANYL	McKESSON	02/27/17	03/07/17
		5/10/17	FENTANYL	McKESSON	5/10/17	05/17/17
		08/09/17	FENTANYL	McKESSON	08/09/17	08/16/17
		10/31/17	FENTANYL	McKESSON	10/31/17	11/09/17
		01/23/18	FENTANYL	McKESSON	01/23/18	01/30/18
		03/26/18	FENTANYL	McKESSON	03/26/18	04/03/18

DEA Power of Attorney

https://www.deaecom.gov/poa.html

Power of Attorney for DEA Forms 222 and Electronic Orders

(Name of registrant) _____

(Address of registrant) _____

_____

(DEA registration number) _____

I, _____ (name of person granting power), the undersigned, who am 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, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

_____(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____(Signature of attorney-in-fact)

Witnesses:

1. _____ (Signature of witness)

2. _____ (Signature of witness)

Signed and dated on _____ (current date).

Notice of Revocation – to be completed only when Power of Attorney is revoked

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. _____ (Signature of witness)

2. _____ (Signature of witness)

Signed and dated on _____ (current date).

POA Revocation

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 _____?_____.

(d) A power of attorney must be executed by:

(1) The registrant, if an individual; a partner of the registrant, if a partnership; or an officer of the registrant, if a corporation, corporate division, association, trust or other entity;

(2) The person to whom the power of attorney is being granted; and

(3) Two witnesses.

(e) A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.

(f) A power of attorney executed under this section may be signed electronically, by any or all of the persons required to sign.

[70 FR 16911, Apr. 1, 2005, as amended at 84 FR 51374, Sept. 30, 2019]

Biennial Inventory Example

_____ SURGERY CENTER

2023 DEA BIENNIAL CONTROLLED SUBSTANCE INVENTORY

C-III – C-V DRUGS

Date:	**Time:**
Beginning of Day: _____ **End of Day:** _____ *(check one)*	
Inventory Performed by: (Licensed staff)	
Inventory Witnessed by: (Licensed staff)	
DEA Registration Number:	
DEA Expiration Date:	

Title 21 CFR Part 1304 1304.11
DEA Reports and Records of Registrants

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

Diazepam 5mg tablet		Tablet
Gabapentin 100mg tablet/capsule		Tablet/Capsule
Ketamine 500mg/10ml injection		Vial
Midazolam 2mg/2ml injection		Vials
Tramadol 50mg tablet		Tablet

Specifics for this form mandated in CFR 1304.11

DEA CIII – CV
Transfer Form Example

_____ **SURGERY CENTER**

C-III – C-V CONTROLLED SUBSTANCE TRANSFER FORM

(Not for C-II transfers which must accompanied by a DEA 222 Form)

Date:	**Staff Member Completing Form:**
Distributing DEA Registrant: *(as listed on DEA License)* • DEA Registrant Legal Name • Registrant Address • DEA Number • Contact Name • Contact Phone Number	
Receiving DEA Registrant: *(as listed on DEA License)* • DEA Registrant Legal Name • Registrant Address • DEA Number • Contact Name • Contact Phone Number	

Drug Name	Drug Strength/Concentration	Drug Form	Unit Form	Quantity of Units
Examples: *Midazolam* *Diazepam*	*Examples:* *2mg/2ml* *5mg*	*Examples:* *Injection* *Tablet*	*Examples:* *Vial* *Tablet*	*Examples:* *20 vials* *100 tablets*

Specifics for this form mandated in CFR

DEA Forms

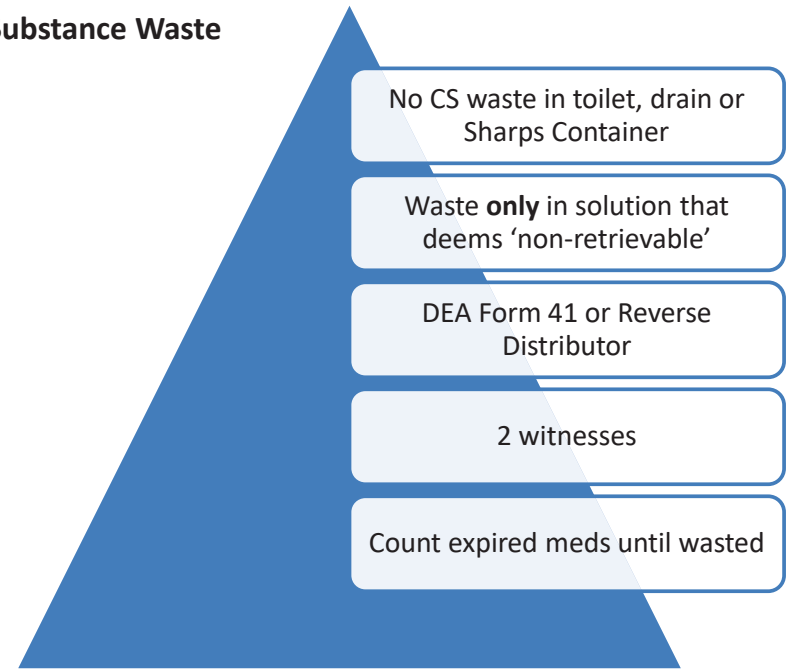
All available at www.deadiversion.usdoj.org

- **DEA Form 106**
  - Theft/Significant Loss
  - Complete once investigation complete
  - Also, report in writing (email) within ***one business day*** ****
  - Work with local DEA Field or Division Office
  - 45 days to complete after discovery of loss – gather all facts

- **DEA Form 41**
  - Destruction process **within facility**
  - Only for **stocked inventory** (not for waste associated with clinical use)
  - Only if waste is 'non-retrievable'
  - No flushing down sink/toilet

- **DEA Form 222**
  - Ordering / Transferring of C-II's ONLY
  - POA
    - Designated by facility in writing
    - Must be rescinded with changes

Controlled Substance Waste



'Non-Retrievable' – " a process that permanently alters the substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable or unusable for all practical purposes. 21 CFR 1300.05(b)

DEA Form 41
For Internal Waste

https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html

- Complete Form Fully
- Waste as 'irretrievable'
- File with narcotic documentation
- Save for 2 years – does not have to be submitted to DEA


Registrant Record of Controlled Substances Destroyed - DEA Form 41

Get Email Updates:

Destruction of Controlled Substances

IMPORTANT NOTICE: Only those persons registered with and authorized by DEA to handle controlled substances may utilize/submit this form.

Registrant Record of Controlled Substances Destroyed - DEA Form 41 (PDF)

INSTRUCTIONS

Registrant Record of Controlled Substances Destroyed - DEA Form 41

It is recommended that registrants review 21 CFR §1317 – Disposal

1. Section A. REGISTRANT INFORMATION:
The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
2. Section B. (1) Inventory:
This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).

OMB APPROVAL NO. 1117-0007 Expiration Date 9/30/2017

U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION

REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED

FORM DEA-41

A. REGISTRANT INFORMATION

Registered Name:		DEA Registration Number:
Registered Address:		
City:	State:	Zip Code:
Telephone Number:		Contact Name:

B. ITEM DESTROYED

1. Inventory

	National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
Examples	*16590-598-60*	*N/A*	*Kadian*	*60mg*	*Capsules*	*60*	*2*	*0*	*120 Capsules*
	0555-0767-02	*N/A*	*Adderall*	*5mg*	*Tablet*	*100*	*0*	*83*	*83 Tablets*
	9050	*B02120312*	*Codeine*	*N/A*	*Bulk*	*1.25 kg*	*N/A*	*N/A*	*1.25 kg*
1.									
2.									
3.									
4.									
5.									
6.									
7.									

2. Collected Substances

	Returned Mail-Back Package	Sealed Inner Liner	Unique Identification Number	Size of Sealed Inner Liner	Quantity of Packages(s)/Liner(s) Destroyed
Examples	*X*		*MBP1106, MBP1108 - MBP1110, MBP112*	*N/A*	*5*
		X	*CRL1007 - CRL1027*	*15 gallon*	*21*
		X	*CRL1201*	*5 gallon*	*1*
1.					
2.					
3.					
4.					
5.					
6.					
7.					

Form DEA-41 *See instructions on reverse (page 2) of form.*

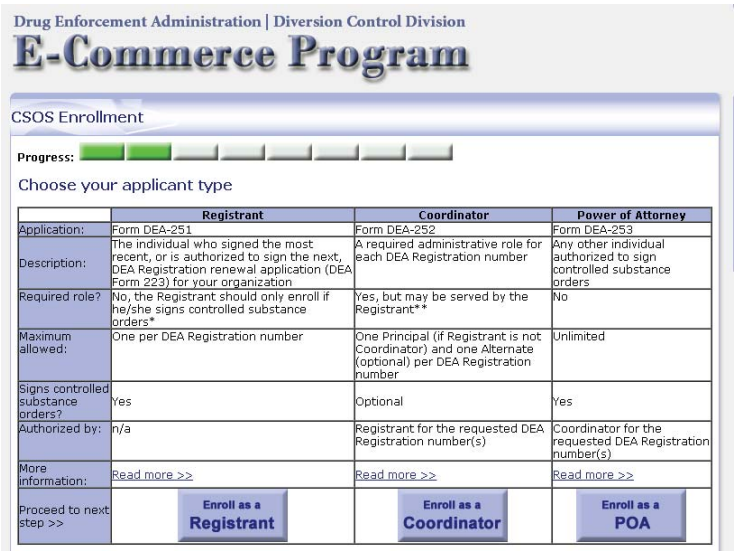
Non-Retrievable waste examples

DEA Registration process

- Medical School
- Graduation Year
- NPI
- State License #
- License Exp Date
- Name of facility / Medical Director
- Email contact- if they move
- Don't let expire!
- New DEA # for all changes to Medical Director
- CSOS breaks
- Must transfer narcotics via invoice and 222
- Initial count
- Keep paperwork on old DEA for 2 years

- Any Medical Director change prompts new DEA #
- Retire prior DEA license with initiation of new DEA
- Transfer controlled substances from old DEA to new DEA
- Perform Initial Inventory count

Controlled Substance Ordering System (CSOS)


Drug Enforcement Administration | Diversion Control Division

E-Commerce Program

CSOS Enrollment

Progress:

Choose your applicant type

	Registrant	Coordinator	Power of Attorney
Application:	Form DEA-251	Form DEA-252	Form DEA-253
Description:	The individual who signed the most recent, or is authorized to sign the next, DEA Registration renewal application (DEA Form 223) for your organization	A required administrative role for each DEA Registration number	Any other individual authorized to sign controlled substance orders
Required role?	No, the Registrant should only enroll if he/she signs controlled substance orders*	Yes, but may be served by the Registrant**	No
Maximum allowed:	One per DEA Registration number	One Principal (if Registrant is not Coordinator) and one Alternate (optional) per DEA Registration number	Unlimited
Signs controlled substance orders?	Yes	Optional	Yes
Authorized by:	n/a	Registrant for the requested DEA Registration number(s)	Coordinator for the requested DEA Registration number(s)
More information:	Read more >>	Read more >>	Read more >>
Proceed to next step >>	Enroll as a Registrant	Enroll as a Coordinator	Enroll as a POA

- Quicker access to shortage meds
- POA in place for each staff member
- ***Must close every CSOS order electrontically***

https://www.deaecom.gov/apprapps.html

DEA INVESTIGATIONS

- DEA investigating more ‘without cause’
- Federal Law Enforcement Agency
- MOA / Fines / License revocation / Prison
- Biennial inventory to current

RESOURCES > Questions & Answers > Suspicious Orders (SORS) Q&A

Suspicious Orders (SORS) Q&A

Suspicious Orders (SORS)

Question: Are DEA-registered manufacturers or distributors required by the CSA or DEA regulations to establish limits (quantitative thresholds) on the amounts of controlled substances, including MOUD, that another DEA registrant can order or dispense?

Answer: No. Neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits.

The CSA, as amended by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act (SUPPORT Act) requires each DEA registrant to: 1) design and operate a system to identify **suspicious orders** for the registrant; 2) ensure that the system complies with applicable Federal and State privacy laws; and 3) upon discovering a suspicious order or series of orders, notify the Administrator of the DEA and the Special Agent in Charge of the Division Office of the DEA for the area in which the registrant is located or conducts business. **21 U.S.C. 832(a)**. Suspicious orders may include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. **21 U.S.C. 802(57)**. Furthermore, all applicants and registrants must maintain effective controls and procedures to guard against theft and diversion. **21 CFR 1301.71(a)**.

To comply with these statutory and regulatory requirements, many DEA-registered manufacturers and distributors establish controlled substance monitoring systems that set thresholds that may limit the amount of a customer’s controlled substance purchases and may prompt a report of a **suspicious order** to DEA. However, whether to set such thresholds (if any) and at what levels are decisions that each manufacturer or distributer may make in the design and implementation of its controlled substance monitoring system. DEA does not have a role in establishing or revising thresholds for controlled substances that manufacturers or distributors may set for their customers as part of the required monitoring systems.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies. **DEA-DC-065, EO-DEA258, January 20, 2023**

https://www.deadiversion.usdoj.gov/sors/index.html

Situation

- New Center / New Staff
- High-Performing RN
- Became ‘lead’ for CRNA’s and Box distribution
- No 2-person verification
- Distractions during process
- Editing logs
- Cameras

Findings / Learned

- Always 2 people involved in box refilling / verification
- Camera placement
- Local Law Enforcement
- DEA Notification / Visit
- State Infectious Disease Dept.
- Board of Nursing
- DEA Memorandum of Agreement

Best Practice or Bad Practice?

https://www.securitymagazine.com/articles/87746-what-is-a-best-practice-and-should-you-deploy-them

Medication Management Best Practices

High Alert / LASA Medications

- Assess/Update Annually
- Include Staff to build lists
- ISMP.org for lists (Develop center-specific)
- Label EVERY storage location (Carts/Boxes.etc)
- Individual Bins / Segregated Storage
- Practice Plans Staff Awareness
- POST LISTS !

Accreditation Bodies

CMS

State Regs

TJC

AAAHC

AAAA

The Joint Commission

2024 Ambulatory Health Care National Patient Safety Goals

(Easy-To-Read)

Identify patients correctly	
NPSG.01.01.01	Use at least two ways to identify patients. For example, use the patient's name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment.
Use medicines safely	
NPSG.03.04.01	Before a procedure, label medicines that are not labeled. For example, medicines in syringes, cups and basins. Do this in the area where medicines and supplies are set up.
NPSG.03.05.01	Take extra care with patients who take medicines to thin their blood.
NPSG.03.06.01	Record and pass along correct information about a patient's medicines. Find out what medicines the patient is taking. Compare those medicines to new medicines given to the patient. Give the patient written information about the medicines they need to take. Tell the patient it is important to bring their up-to-date list of medicines every time they visit a doctor.
Prevent infection	
NPSG.07.01.01	Use the hand cleaning guidelines from the Centers for Disease Control and Prevention or the World Health Organization. Set goals for improving hand cleaning.
Improve health care equity	
NPSG.16.01.01	Improving health care equity is a quality and patient safety priority. For example, health care disparities in the patient population are identified and a written plan describes ways to improve health care equity.
Prevent mistakes in surgery	
UP01.01.01	Make sure that the correct surgery is done on the correct patient and at the correct place on the patient's body.
UP01.02.01	Mark the correct place on the patient's body where the surgery is to be done.
UP01.03.01	Pause before the surgery to make sure that a mistake is not being made.

2024 TJC NPSG

- Patient Identifiers
- Labeling!!
- Anticoagulation Therapy
- Medication Lists
- Hand Cleaning
- Correct Surgery Site

https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2024/ahc-npsg-simple-2024.pdf

Top ASC
Medication Management Findings

- Storage per manufacturer
- Medication Security
- Medication handling / waste
- Unauthorized medication access
- Labeling!
- Expired medication management
- Concentrated Electrolytes
- Patient's own medications / Samples
- Therapeutic Duplication of orders

https://www.wolterskluwer.com/en/expert-insights/ten-things-your-joint-commission-surveyor-is-looking-for

Common TJC Finding : Therapeutic Duplication

- Order Sets include clear indications for each PRN medication
- Nurse contacts Provider for clarification when duplications are identified
- PRN orders – Be specific with parameters
- Use specific pain scale parameters when dosing
- Clarify sequencing – " for n/v. If still n/v after 30 minutes, administer…"
- Scope of Practice – Nurse should not be determining dose without written plan

Clinical Emergency Management

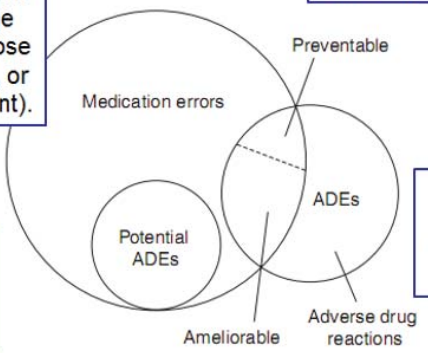
State requirements MHAUS.org (Malignant Hyperthermia) Medical Director & Anesthesia MEC Approval of changes Drill Annually	Ryanodex / Dantrolene Label Carts/Boxes for HA/LASA Pre-Mixed Infusions (Magnesium Dobutamine, KCL, Dopamine, etc.) Tubing Compatibility Pump Availability	All Clinical Scenarios: *Anaphylaxis* *Cardio-Pulmonary* *Methemoglobinemia* *Seizures* *Anesthetic Toxicity* Pediatric & Adult Preparation

Adverse Drug Event / Adverse Drug Reaction Management

ADE / ADR Definitions

Medication Error: An event that may cause or lead to inappropriate medication use or patient harm (for example: the wrong medication or dose prescribed, dispensed, or administered to a patient).

Adverse Drug Event (ADE): An injury due to a medication either from a medication error ***or*** ADR.



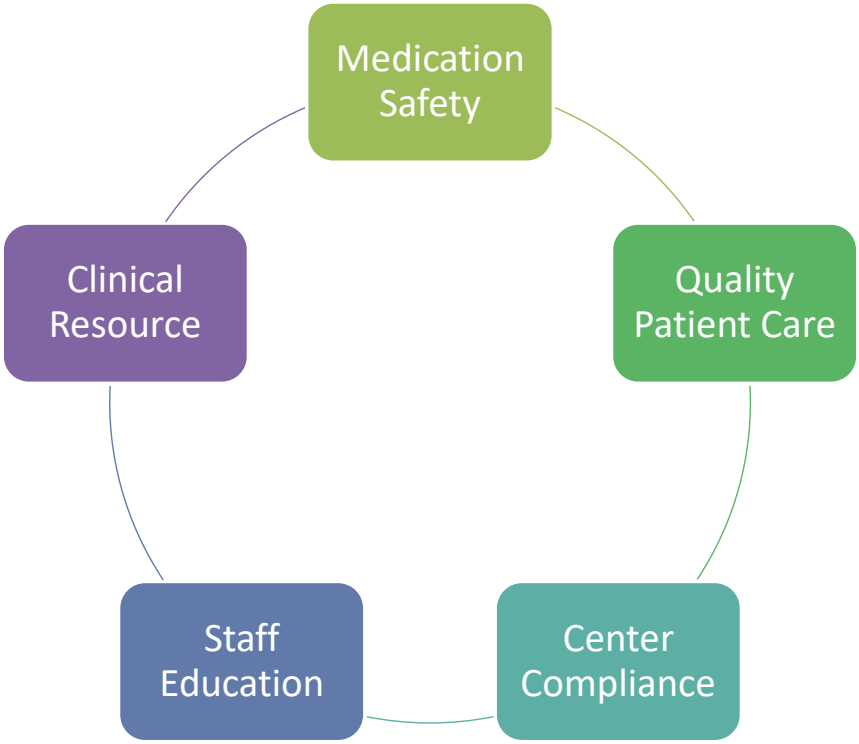
Near Miss/Near Hit/Close Call: An error discovered prior to reaching a patient.

Adverse Drug Reaction (ADR): Non-preventable reactions due to side-effects or allergic reactions.

Figure 1 Relationship between adverse drug events (ADEs), potential ADEs, and medication errors.

Morimoto, T, et al. Adverse Drug Events and Medication Errors: Detection and Classification Methods. *Qual Saf Health Care* 2004;13:306-314

Your Consultant Pharmacist



Consultant Pharmacist

- Contracted for services
- Competencies in TJC, AAAHC, QuadA, etc., CMS, State Laws, AORN, HIPPA
- Expert in Patient Safety, Compliance, and Quality Care
- Available for in-services to all staff-- i.e., Anesthesia, Nursing
- Creates 'closed-loop' survey and review processes
- Performs controlled-substance audits
- Provides regular center audits for Nurse Administrators and ASC Admin

SURGERY CENTER 2025 MEDICATION MANAGEMENT MONTHLY REVIEW												
(C) = COMPLIANCE (N) = NON-COMPLIANCE (BUD) = BEYOND-USE-DATE (AC) = ANESTHESIA CART	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
MEDICATION STORAGE												
Controlled Substance receiving documentation complete (signed/dated invoices & completed CSOS/DEA 222 forms)												
Medication storage areas are clean, organized, appropriately lit, correct temperatures & free of food and clutter												
Medications storage bins are clearly labeled with drug name, strength & concentration on shelves, boxes & carts												
High-Alert (HA), Look Alike/Sound Alike (LASA), & Hazardous medications labeled w/ lists posted & stored properly												
Neuromuscular blockers are stored in labeled (HA), lidded container (lidded not required in Anesthesia Cart)												
Expired medications are removed from inventory & quarantined until processed in a timely manner												
Medications are stored to ensure stability, sterility & safety as noted in Package Insert & from manufacturer												
Medications are behind locks and inaccessible by non-authorized persons as center policy allows												
Controlled medications are locked and inaccessible at all times by non-authorized individuals												
Emergency Carts are stocked, in date, sealed w/ break-away lock & and accompanied by updated Expiration Log												
Sanitation-Expiration Log in Medication Management Book is initialed by assigned staff for prior months												
Refrigerator/Freezer temps are in range of 36°F – 46°F & documented with NIST-certified, in-date thermometer												
MEDICATION PREPARATION												
Prepared medications are labeled with name, strength or concentration, initials and Beyond-Use Date (exp time)												
Single-use / Single-patient injectables are discarded after initial spike and used on only one patient												
Spiked Multi-dose injectable vials are labeled with BUD or discarded if used in a procedural area												
Open ophthalmic ointments and drops are dated with BUD *(28 days from opening unless sterility is compromised)*												
IV fluids removed from outer wrapper are labeled w/ BUD *(28 day- not written on bag)* & dated w/ BUD in warmer												
ANESTHESIA CARTS/BOXES												
Succinylcholine*(14 days)*, **Rocuronium***(60 days)*, **and Vasopressin***(12 months)* are dated w/ BUD on carts												
Opened eye ointments & drops are dated with BUD (*28 days*) or discarded after each use												
Controlled medications are inaccessible at all times by non-authorized individuals												
Prepared medications are labeled with name, strength or concentration, initials and Beyond-Use Date (exp time)												
Injectable medications drawn in syringes or compounded are discarded after 1hr from prep time or after each case												
Spiked injectables, including narcotics, are discarded after each case and not used on more than one patient												

MEDICATION MANAGEMENT
SANITATION/EXPIRATION CHECK

The monthly procedure for the areas listed above is as follows:

- Check thoroughly for all expired drugs. Pull any expired drugs and place in the 'Expired Medication' bin. Expired meds should be reviewed for reordering
- All medications removed from their original containers should be labeled properly. If not, discard in a sharps container
- Clean and straighten any area that houses medications. This includes **labeling all medication storage bins/drawers/shelves** to prevent medication errors
- Review any medications that are no longer used in the center to ensure medications present are listed on the center's formulary and are currently used within the practice of the facility

YEAR:

AREA	ASSIGNED STAFF PERSON	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC
Procedure Room 1													
Narcotic Room													
Anesthesia Workroom													
Medication Refrigerator													
OR 1													
OR 2													
Emergency Cart													

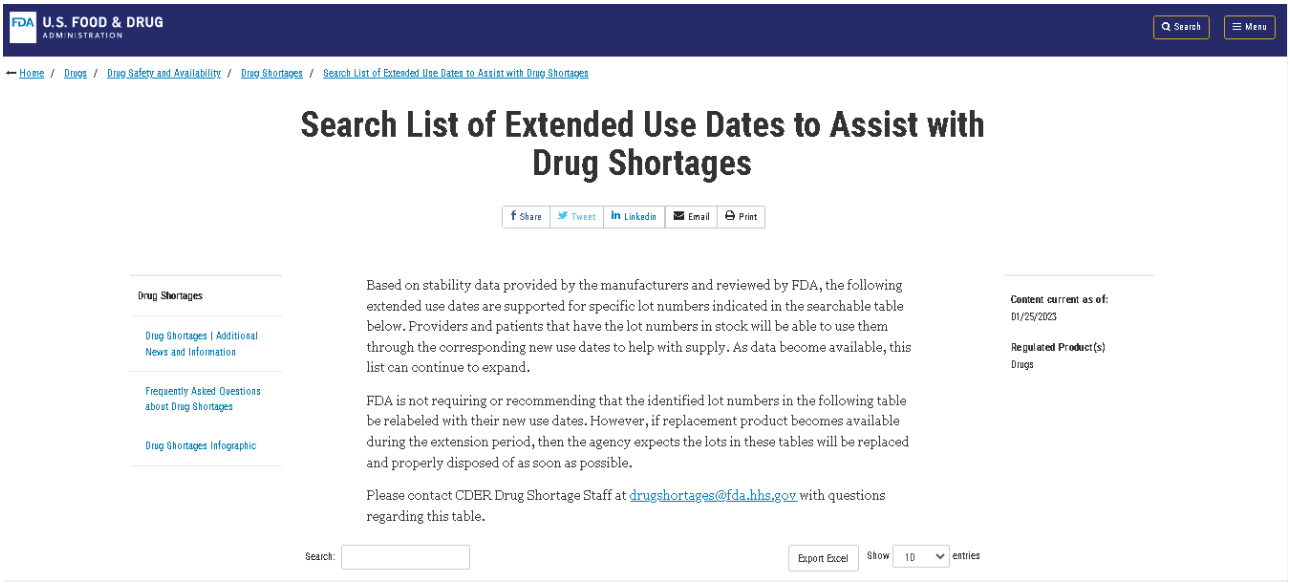
Specific Beyond-Use Dates Out of Refrigeration

Succinylcholine 14 days	Cisatracurium 21 days	Rocuronium 60 days
Atracurium 14 days	Vasopressin 12 months	

Common TJC Finding – Storage per manufacturer

Temperature Monitoring Refrigerators / Warmers / Rooms

- Perpetual monitoring/tracking system
- Documentation
- Audible alarm ON
- Process for excursions
  - Hold product
  - Contact manufacturer
  - Documentation in writing
- Thermometers In-Date
  - NIST-certified
- Staff awareness of process
- Monitor room temp if heat-producing equipment in med rooms



https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

FDA RESOURCE – EXTENDED EXPIRATION DATES

Product	Company	NDC Number	Lot Number	Expiration Date (Labeled)	Extended Use Date
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	160350D	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	160900D	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	161400D	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	161450D	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	162000D	1-Apr-2022	1-Apr-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	190600D	1-Jul-2022	1-Jul-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	190950D	1-Jul-2022	1-Jul-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	191350D	1-Jul-2022	1-Jul-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	180750D	1-Jun-2022	1-Jun-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	181450D	1-Jun-2022	1-Jun-2023

Showing 1 to 10 of 169 entries

Previous 1 2 3 4 5 ... 17 Next

https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

Search List of Extended Use Dates to Assist with Drug Shortages | FDA					
Product	Company	NDC Number	Lot Number	Expiration Date (Labeled)	Extended Use Date
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	18145DD	1-Jun-2022	1-Jun-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	18330DD	1-Jun-2022	1-Jun-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17100DD	1-May-2022	1-May-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17150DD	1-May-2022	1-May-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17210DD	1-May-2022	1-May-2023
Diltiazem Hydrochloride for Injection, 100 mg, single dose vial, tray of 10	Hospira, a Pfizer company	0409-4350-03	17350DD	1-May-2022	1-May-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19058DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19060DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19061DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19062DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19063DK	1-Apr-2022	1-Apr-2023
Epinephrine Injection, 1 mg/10 mL (0.1 mg/mL) glass syringe, individual	Hospira, a Pfizer company	0409-4921-20	19223DK	1-Apr-2022	1-Apr-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0030921	28-Feb-2023	31-Aug-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0040921	28-Feb-2023	31-Aug-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0050921	28-Feb-2023	31-Aug-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0120621	30-Nov-2022	31-May-2023
Etomidate injection, 20 mg/10 mL (2 mg/mL), single dose vial, carton of 10	in Steriles (Fresenius Kabi la	65219-445-10	G0150621	30-Nov-2022	31-May-2023
Fludarabine phosphate injection, 50 mg/2 mL (25 mg/mL), single-dose vial,	Sagent Pharmaceuticals	25021-242-02	100020734	Jan-2023	Jul-2023
Heparin Sodium 25,000 units/250 mL (100 units/mL) in 5% Dextrose Injecti	Hospira, a Pfizer company	0409-7793-62	32303KL00	1-Aug-2023	1-Mar-2024
Heparin Sodium Injection, 25,000 units/250 mL (100 units/mL) in 5% Dextro	Hospira, a Pfizer company	0409-7793-62	33403KL00	1-Sep-2023	1-Apr-2024
Heparin Sodium Injection, 25,000 units/250 mL (100 units/mL) in 5% Dextro	Hospira, a Pfizer company	0409-7793-62	31201KL00	1-Jul-2023	1-Feb-2024
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	14293DK00	1-Feb-2022	1-Feb-2023
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	14422DK00	1-Feb-2022	1-Feb-2023
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	13140DK00	1-Jan-2022	1-Jan-2023
Potassium Acetate Injection, 100 mEq/50 mL (2 mEq/mL); pharmacy bulk pa	Hospira, a Pfizer company	0409-3294-51	17377DK00	1-May-2022	1-May-2023

Extended Expiration List – Exportable

https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages

Expiration Extensions

FDA Approval required MEC review/approval	Re-label all products with new expiration date Replace when product is available – FDA expectation	Keep documentation on file Minimize if possible

Labeling Requirements

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

- **Drug Name/Diluent/Strength**
- **Initials of preparer**
- Prep Time
- **BUD**

The Joint Commission

- **Medication Name/Strength**
- Date of Prep
- **BUD**
- 2 patient identifiers

USP <797>

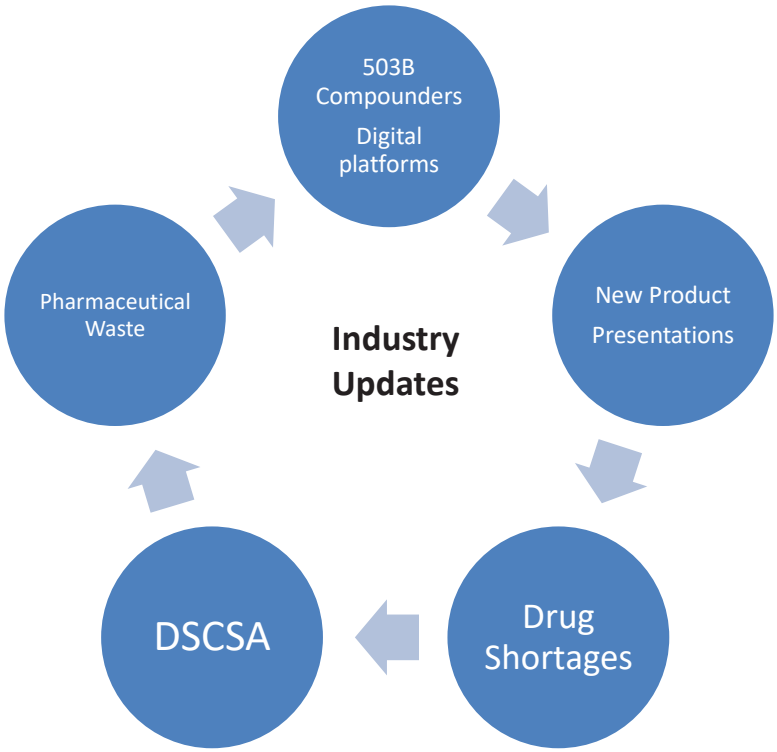
- **Medication(s) / Diluent(s) names**
- **Initials of preparer**
- **BUD (Packager Insert or 4 hours from prep initiation**

Best Practice or Bad Practice?

Other ASC Practice Pearls

- Replace Drug Information Books with each new Edition (ISMP)
- Review Policies / Write Policy when required
- 5 Rights – Patient/Drug/Dose/Route/Time
- Antimicrobial Stewardship
- Current trends – Vaping of Anesthesia Gases / Propofol

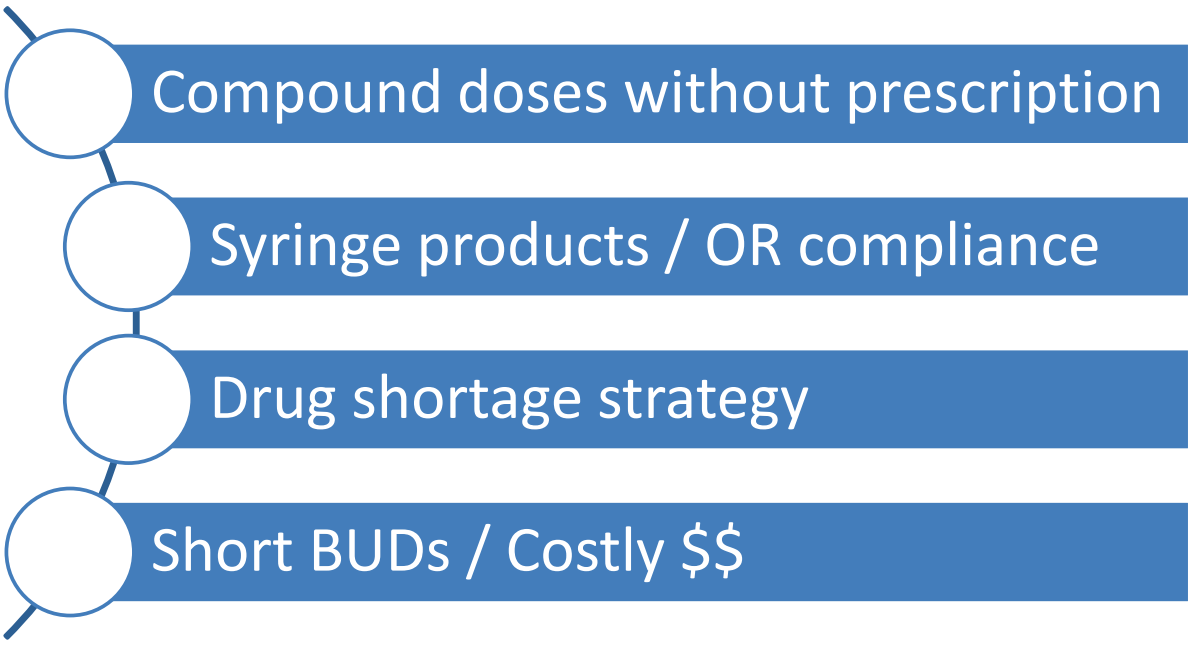
Industry Updates



NEW DRUG SOURCING OPTIONS

- Digital Pharmaceutical Sourcing
  - ‘Amazon’ – like
  - Shop multiple options in catalog
  - 503B listings
  - Price Bidding
  - Examples: Medigi™ / MedShorts™ / GraphiteRx™

503B Compounders



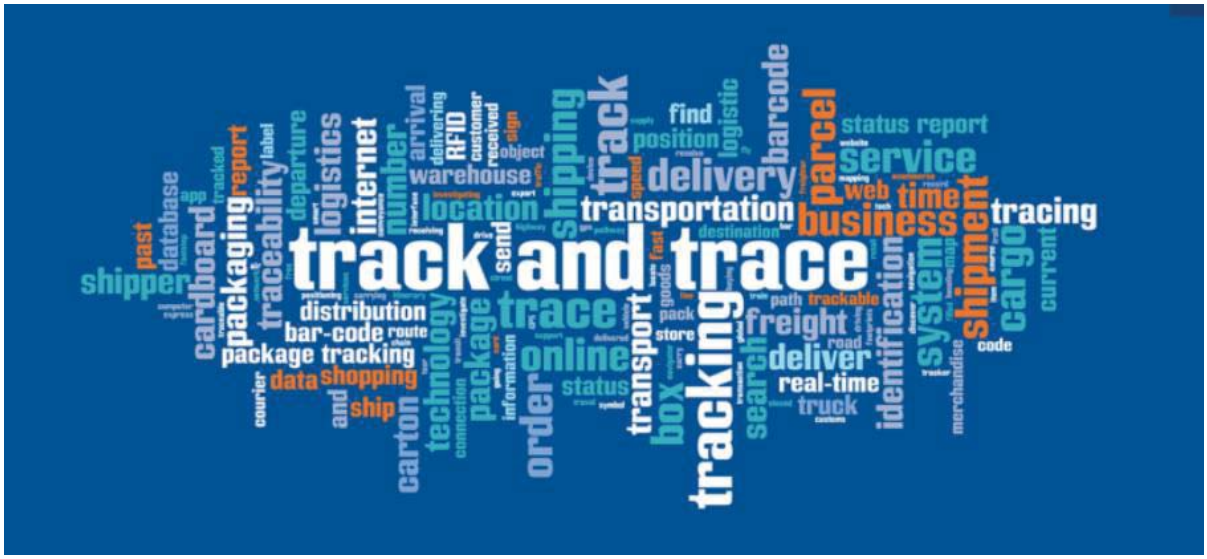
Pharmaceutical Waste in the ASC

https://www.danielshealth.com/knowledge-center/know-which-bin

- **Hazardous / Non-Hazardous**
- **Various bins for collection**
- **All pharmaceutical waste except controlled substances**
- **Consult with your Waste Vendor for assessment and strategy specific to your Formulary**
- **Sharps not acceptable source for Pharmaceutical Waste**
- **Lidded / Locked when possible**
- **P-listed and U-listed drugs managed specifically as dictated by State law and waste company**

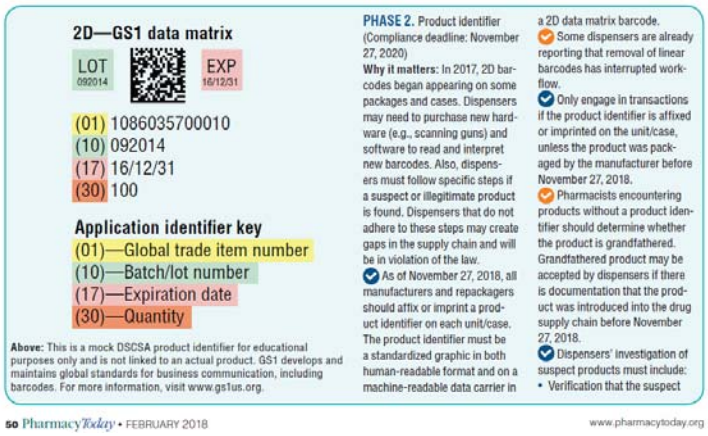
Pharmaceutical Waste Streams

Drug Supply Chain & Security Act



GO-LIVE- NOVEMBER 27, 2024

https://www.dcatvci.org/features/the-next-deadline-for-drug-supply-chain-security/



2D—GS1 data matrix

LOT 092014 EXP 16/12/31

(01) 1086035700010
(10) 092014
(17) 16/12/31
(30) 100

Application identifier key

(01)—Global trade item number
(10)—Batch/lot number
(17)—Expiration date
(30)—Quantity

Above: This is a mock DSCSA product identifier for educational purposes only and is not linked to an actual product. GS1 develops and maintains global standards for business communication, including barcodes. For more information, visit www.gs1us.org.

PHASE 2. Product identifier (Compliance deadline: November 27, 2020)

Why it matters: In 2017, 2D barcodes began appearing on some packages and cases. Dispensers may need to purchase new hardware (e.g., scanning guns) and software to read and interpret new barcodes. Also, dispensers must follow specific steps if a suspect or illegitimate product is found. Dispensers that do not adhere to these steps may create gaps in the supply chain and will be in violation of the law.

As of November 27, 2018, all manufacturers and repackagers should affix or imprint a product identifier on each unit/case. The product identifier must be a standardized graphic in both human-readable format and on a machine-readable data carrier in a 2D data matrix barcode.

Some dispensers are already reporting that removal of linear barcodes has interrupted workflow.

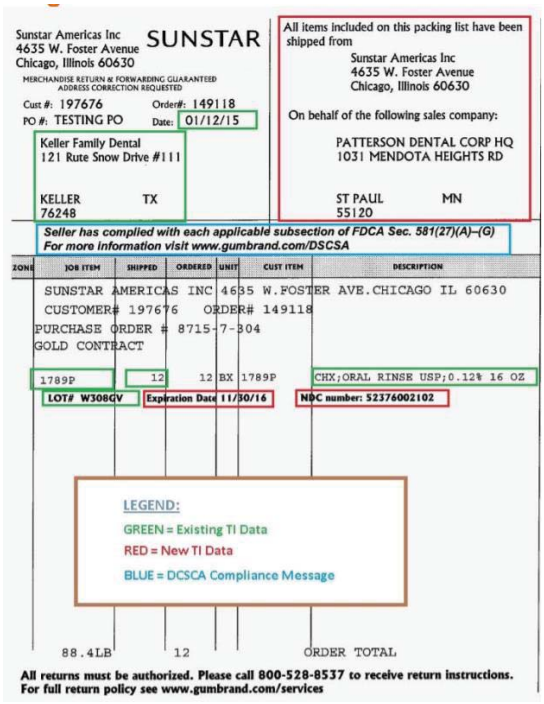
Only engage in transactions if the product identifier is affixed or imprinted on the unit/case, unless the product was packaged by the manufacturer before November 27, 2018.

Pharmacists encountering products without a product identifier should determine whether the product is grandfathered. Grandfathered product may be accepted by dispensers if there is documentation that the product was introduced into the drug supply chain before November 27, 2018.

Dispensers' investigation of suspect products must include:
- Verification that the suspect

DSCSA – "T3"

Transaction Information (TI)
Transaction History (TH)
Transaction Statement (TS)



Sunstar Americas Inc
4635 W. Foster Avenue
Chicago, Illinois 60630

SUNSTAR

MERCHANDISE RETURN & FORWARDING GUARANTEED
ADDRESS CORRECTION REQUESTED

Cust #: 197676 Order#: 149118
PO #: TESTING PO Date: 01/12/15

Keller Family Dental
121 Rute Snow Drive #111
KELLER TX
76248

All items included on this packing list have been shipped from
Sunstar Americas Inc
4635 W. Foster Avenue
Chicago, Illinois 60630

On behalf of the following sales company:
PATTERSON DENTAL CORP HQ
1031 MENDOTA HEIGHTS RD
ST PAUL MN
55120

Seller has complied with each applicable subsection of FDCA Sec. 581(27)(A)–(G)
For more information visit www.gumbrand.com/DSCSA

ZONE	JOB ITEM	SHIPPED	ORDERED	UNIT	CUST ITEM	DESCRIPTION

SUNSTAR AMERICAS INC 4635 W.FOSTER AVE.CHICAGO IL 60630
CUSTOMER# 197676 ORDER# 149118
PURCHASE ORDER # 8715-7-304
GOLD CONTRACT

1789P 12 12 BX 1789P CHX;ORAL RINSE USP;0.12% 16 OZ
LOT# W308GV Expiration Date 11/30/16 NDC number: 52376002102

LEGEND:
GREEN = Existing TI Data
RED = New TI Data
BLUE = DCSCA Compliance Message

88.4LB 12 ORDER TOTAL

All returns must be authorized. Please call 800-528-8537 to receive return instructions.
For full return policy see www.gumbrand.com/services

Pharmacy Today : February 2018 / www.pharmacytoday.org

- Policy / SOP
- Authorized Trading Partners
  - Licensure -- update annually through Board of Pharmacy
  - Validate prior to using
- Retention of T3 -- 6 years minimum
  - Wholesalers or Third-Party sources
  - Have contract to save data
- Validation / Verification
  - Process as receiving product
- Process for Suspect or Illegitimate Product
  - Recognition
  - Quarantine
  - Investigation
  - Notification
- T3 for borrowing / loaning or transfers to other facilities
  - Ownership / Possession
  - Specific patient needs versus inventory needs
- GLN required for your Ship-To location
- Work with your Consultant Pharmacist

DSCSA Summary

https://www.ipcrx.com/pharmacy-blog/pharmacy-services/dscsa-compliance-november-2023/

Best Practice or Bad Practice?

https://www.ismp.org/sites/default/files/attachments/2018-01/EntireAssessmentWorkbook.pdf

https://www.ismp.org/resources/medication-safety-self-assessmentr-perioperative-settings

BEST PRACTICE 4 (ARCHIVED)

ARCHIVED Best Practice

See page 18

Ensure that all oral liquid medications that are not commercially available in unit dose packaging are dispensed by the pharmacy in an oral syringe or an enteral syringe that meets the International Organization for Standardization (ISO) 80369 standard, such as ENFit.

BEST PRACTICE 5 (ARCHIVED)

ARCHIVED Best Practice

See page 19

Purchase oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale.

BEST PRACTICE 6 (ARCHIVED)

ARCHIVED Best Practice

See page 20

Eliminate glacial acetic acid from all areas of the hospital.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 7:

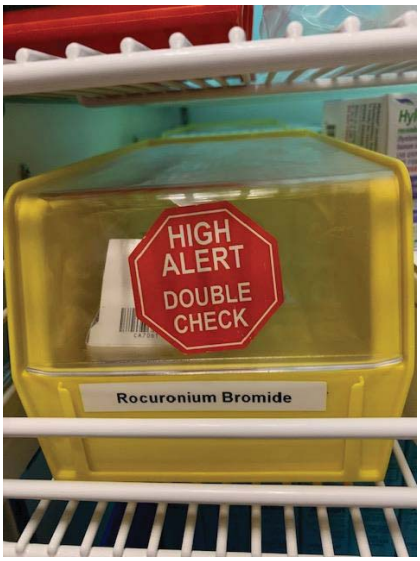
Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization.

- Eliminate the storage of NMBs in areas of the hospital where they are not routinely needed.
- In patient care areas where they are needed (e.g., intensive care unit), place NMBs in a sealed box or, preferably, in a rapid sequence intubation (RSI) kit.
- Limit availability in automated dispensing cabinets (ADCs) to perioperative, labor and delivery, critical care, and emergency department (ED) settings; in these areas, store NMBs in a rapid sequence intubation (RSI) kit, or locked-lidded ADC pockets/drawers.
- Segregate NMBs from all other medications in the pharmacy by placing them in separate lidded containers in the refrigerator or other secure, isolated storage area.
- Place auxiliary labels on all storage bins and/or ADC pockets and drawers that contain NMBs as well as all final medication containers of NMBs (e.g., syringes, intravenous (IV) bags) that state: **"WARNING: CAUSES RESPIRATORY ARREST – PATIENT MUST BE VENTILATED"** or **"WARNING: PARALYZING AGENT – CAUSES RESPIRATORY ARREST"** or **"WARNING: CAUSES RESPIRATORY PARALYSIS – PATIENT MUST BE VENTILATED"** to clearly communicate that respiratory paralysis will occur and ventilation is required.*

Exception: The auxiliary label practice excludes anesthesia-prepared syringes of NMBs.

* Other acceptable alternatives to labeling storage bins and/or ADC pockets are to affix an auxiliary warning label (in addition to the manufacturer's warning on the caps and ferrules) directly on all vials and/or other containers stocked in storage locations, or by displaying a warning on the ADC screen, (e.g., "Patient must be intubated to receive this medication") that interrupts all attempts to remove a neuromuscular blocker via a patient's profile or on override. The warning should require the user to enter or select the purpose of the medication removal ("other" should not be a choice) and verify that the patient is (or will be) manually or mechanically ventilated.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf



BEST PRACTICE 8:

a) Administer medication infusions via a programmable infusion pump utilizing dose error-reduction systems*.

b) Maintain a compliance rate of greater than 95% for the use of dose error-reduction systems.

c) Monitor compliance with use of smart pump dose error-reduction software on a monthly basis.

d) If your organization allows for the administration of an intravenous (IV) bolus or a loading dose from a continuous medication infusion, use a smart pump that allows programming of the bolus (or loading dose) and continuous infusion rate with separate limits for each.

- Allocate resources for ongoing maintenance, updating, and testing of the software and drug library for all smart infusion pumps.
- Ensure drug library content is consistent with the drug information and nomenclature (e.g., drug name, dosing units, dosing rate) in the electronic health record.
- Plan for the implementation of bi-directional (i.e., auto-programming† and auto-documentation‡) smart infusion pump interoperability with the electronic health record.

This *Best Practice* applies to all hospital settings, both inpatient and outpatient (e.g., magnetic resonance imaging [MRI] department, emergency department, outpatient infusion clinics), and to all situations in which medications are infused by the IV or epidural route, including anesthesia use and patient-controlled analgesia (PCA). The only exception is for small volume vesicant infusions (i.e., chemotherapy vesicants) which, when administered via the peripheral route, should only be infused by gravity and NOT by an infusion/syringe pump.

* Dose error-reduction systems (DERS): Refers to the integral computer software in smart infusion pumps intended to aid in prevention of infusion programming-related errors and warn users of potential over- or under-delivery of a medication or fluid by checking programmed doses/rates against facility configurable preset limits specific to a medication, fluid, and to a clinical application (e.g., epidural administration) and/or location (e.g., neonatal intensive care unit, medical/surgical unit).

† Auto-programming: Automatic programming of infusion parameters from the electronic health record system to the smart infusion pump (which are then verified, and the infusion is started manually by the practitioner) after use of the barcode medication administration system to associate the patient, fluid container (e.g., bag, bottle, syringe), and pump channel.

‡ Auto-documentation (also known as auto-charting or infusion documentation): Sending infusion information such as intake data, dose/rate changes, and infusion stop time, to the electronic health record system for manual clinician confirmation to enable accurate recording of this information to the patient's record after the infusion is started.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 9:

Ensure all appropriate antidotes, reversal agents, and rescue agents are readily available. Have standardized protocols and/or coupled order sets in place that permit the emergency administration of all appropriate antidotes, reversal agents, and rescue agents used in the facility. Have directions for use/administration readily available in all clinical areas where the antidotes, reversal agents, and rescue agents are used.

- Identify which antidotes, reversal agents, and rescue agents can be administered immediately in emergency situations to prevent patient harm.
- Use this list to develop appropriate protocols or coupled order sets to ensure that the above *Best Practice* is met.

Rationale:

The goal of this *Best Practice* is to ensure that when an antidote, reversal agent, or rescue agent is known for a drug that has a high potential to cause an adverse reaction, or if a toxic dose is inadvertently administered, the agent is readily available and can be administered without delay. Some medications have a high potential to cause an adverse reaction even when the appropriate dose is administered (e.g., iron dextran). Adverse effects can also occur if an overdose of a medication is accidentally administered. In both cases, the reaction can be life-threatening, and sometimes immediate intervention is needed. For some drugs, an antidote, reversal agent, or rescue agent may exist to counteract the reaction. For example, naloxone counteracts the effects of opioids, flumazenil counteracts benzodiazepines, lipid emulsions counteract the cardiotoxic effects of local anesthetics, and uridine triacetate counteracts the toxic effects of fluorouracil.

ISMP has received reports of death and serious harm because there was a delay in the administration of the appropriate antidote, reversal agent, or rescue agent (e.g., **EPINEPH**rine for anaphylaxis). Known antidotes, reversal agents, and rescue agents must be routinely available and, in certain situations, stored in areas where these high-risk medications are administered. In addition, it is important to have standardized protocols or coupled order sets so qualified staff can treat the reaction/overdose without waiting for an order from the prescriber. Also, the directions for use should be available near where these agents are stored to avoid a delay or improper use and administration of the agent.

Best Practice 9 First Introduced:
2016-2017

Related *ISMP Medication Safety Alerts!*:
July 1, 2010; April 8, 2010; March 11, 2010; February 22, 2007; January 11, 2007; December 14, 2006; November 3, 1999; September 10, 1999.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 10 (ARCHIVED)

ARCHIVED Best Practice

See page 21

Eliminate all 1,000 mL bags of sterile water (labeled for "injection," "irrigation," or "inhalation") from all areas outside of the pharmacy.

BEST PRACTICE 11:

When compounding sterile preparations, perform an independent verification to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container.

- Specifically, eliminate the use of proxy methods of verification for compounded sterile preparations of medications (e.g., the "syringe pull-back method," checking a label rather than the actual ingredients).
- Except in an emergency, perform this verification in all locations where compounded sterile preparations are made, including patient care units.
- Use technology to assist in the verification process (e.g., machine-readable coding [e.g., barcoding scanning, radio frequency identification] of ingredients, gravimetric verification, robotics, intravenous [IV] workflow software) to augment the manual processes. *When technology is in use, it is important that processes are in place to ensure it is maintained, the software is updated, and that the technology is always used in a manner that maximizes the medication safety features of these systems.*

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 13:

Eliminate injectable promethazine from the formulary.

- Remove injectable promethazine from all areas of the organization including the pharmacy.
- Classify injectable promethazine as a non-stocked, non-formulary medication.
- Implement a medical staff-approved automatic therapeutic substitution policy to convert all injectable promethazine orders to another antiemetic.
- Remove injectable promethazine from all medication order screens, and from all order sets and protocols.

This *Best Practice* includes not using intramuscular administration of promethazine because this can also cause tissue damage if accidentally injected intraarterially.

Rationale:

The goal of this *Best Practice* is to eliminate the risk of serious tissue injuries and amputations from the inadvertent arterial injection or intravenous (IV) extravasation of injectable promethazine. ISMP brought attention to this serious issue in August 2006 and conducted a survey to determine the prevalence of the issue. Of the nearly 1,000 responses to the survey, 1 in 5 reported awareness of such an occurrence in their facility during the prior 5 years. The US Food and Drug Administration (FDA) requires the manufacturer to include strong warnings about the risk of inadvertent intraarterial injection or perivascular extravasation of this drug in the package insert. Injectable promethazine has been included on the ***ISMP List of High-Alert Medications in Acute Care Settings*** (www.ismp.org/node/103) since 2007.

In 2009, ISMP recommended removal of injectable promethazine from an organization's formulary, if possible, and use of safer alternatives such as 5-HT 3 antagonists (e.g., ondansetron). However, these products were significantly higher in cost at the time. Since then, these alternative injectable antiemetics have become available as generic products and are significantly less costly. Thus, injectable promethazine has been used less frequently, and for safety, should now be removed from all formularies.

Best Practice 13 First Introduced:
2018-2019

Related *ISMP Medication Safety Alerts!*:

June 27, 2013; October 8, 2009; September 24, 2009; October 9, 2008; November 2, 2006; **August 10, 2006**.

https://www.ismp.org/system/files/resources/2022-02/2022-2023%20TMSBP%20final.pdf

BEST PRACTICE 14:

Seek out and use information about medication safety risks and errors that have occurred in other organizations outside of your facility and take action to prevent similar errors.

- Appoint a single healthcare professional (preferably a medication safety officer) to be responsible for oversight of this entire activity in the hospital.
- Identify reputable resources (e.g., ISMP, The Joint Commission, ECRI, patient safety organizations, state agencies) to learn about risks and errors that have occurred externally.
- Establish a formal process for monthly review of medication risks and errors reported by external organizations, with a new or existing interdisciplinary team or committee responsible for medication safety. The process should include a review of the hospital's current medication use systems (both manual and automated) and other data such as internal medication safety reports to determine any potential risk points that would allow a similar risk or error to occur within the hospital.
- Determine appropriate actions to be taken to minimize the risk of these types of errors occurring in the hospital.
- Document the decisions reached and gain approval for required resources as necessary.
- Share the external stories of risk and errors with all staff, along with any changes that will be made in the hospital to minimize their occurrence, and then begin implementation.
- Once implemented, periodically monitor the actions selected to ensure they are still being implemented and are effective in achieving the desired risk reduction. Widely share the results and lessons learned within the facility.

BEST PRACTICE 15:

Verify and document a patient's opioid status (naïve versus tolerant*) and type of pain (acute versus chronic) before prescribing and dispensing extended-release and long-acting opioids.

- Default order entry systems to the lowest initial starting dose and frequency when initiating orders for extended-release and long-acting opioids.
- Alert practitioners when extended-release and long-acting opioid dose adjustments are required due to age, renal or liver impairment, or when patients are prescribed other sedating medications.
- Eliminate the prescribing of fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain.
- Eliminate the storage of fenta**NYL** patches in automated dispensing cabinets or as unit stock in clinical locations where acute pain is primarily treated (e.g., in the emergency department, operating room, postanesthesia care unit, procedural areas).

Fenta**NYL** patches are for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Extended-release formulations are for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

*** Opioid-tolerant patient:** Opioid tolerance is defined by the following markers: Patients receiving, for 1 week or longer, at least: 60 mg oral morphine/day; 25 mcg transdermal fenta**NYL**/hour; 30 mg oral oxy**CODONE**/day; 8 mg oral **HYDRO**morphone/day; 25 mg oral oxy**MOR**phone/day; 60 mg oral **HYDRO**codone/day; or an equianalgesic dose of another opioid, including heroin and/or non-prescribed opioids.

Rationale:

The goal of this *Best Practice* is to support appropriate prescribing of extended-release and long-acting opioid medications and prevent death and serious patient harm from inappropriate use of these medications. A secondary goal is to specifically prevent the inappropriate use of fenta**NYL** patches to treat acute pain in patients who are opioid-naïve. *Fenta**NYL** patches were the highest-ranking drug involved in serious adverse drug events (ADEs) reported to the US Food and Drug Administration (FDA) from 2008 through 2010.* ISMP continues to receive reports, including fatalities, due to the prescribing, dispensing, and administration of fenta**NYL** patches to treat acute pain in opioid-naïve patients.

Best Practice 15 First Introduced:
2020-2021

Related *ISMP Medication Safety Alerts!*:

January 28, 2021; March 11, 2021; January 26, 2017; October 20, 2016; November 6, 2014; October 9, 2014; October 17, 2013; **May 30, 2013;** June 17, 2010; May 20, 2010; February 11, 2010; October 8, 2009; November 6, 2008; July 12, 2007; **June 28, 2007;** August 11, 2005; May 20, 2004; April 18, 2001.

NEW Best Practice

NEW BEST PRACTICE 17:

Safeguard against errors with oxytocin use.

a) **Require the use of standard order sets for prescribing oxytocin antepartum and/or postpartum that reflect a standardized clinical approach to labor induction/augmentation and control of postpartum bleeding.**

b) **Standardize to a single concentration/bag size for both antepartum and postpartum oxytocin infusions (e.g., 30 units in 500 mL Lactated Ringers).**

c) **Standardize how oxytocin doses, concentration, and rates are expressed. Communicate orders for oxytocin infusions in terms of the dose rate (e.g., milliunits/minute) and align with the smart infusion pump dose error-reduction system (DERS).**

d) **Provide oxytocin in a ready-to-use form. Boldly label both sides of the infusion bag to differentiate oxytocin bags from plain hydrating solutions and magnesium infusions.**

e) **Avoid bringing oxytocin infusion bags to the patient's bedside until it is prescribed and needed.**

Rationale:

The goal of this *Best Practice* is to prevent errors associated with oxytocin use. Intravenous (IV) oxytocin is used antepartum to induce labor in patients with a medical indication, to stimulate or reinforce labor in selected cases of uterine inertia, and as an adjunct in the management of an incomplete, inevitable, or elective abortion. Used postpartum, IV oxytocin is indicated to produce uterine contractions during expulsion of the placenta and to control postpartum bleeding or hemorrhage. However, improper administration of oxytocin can cause hyperstimulation of the uterus, which in turn can result in fetal distress, the need for an emergency cesarean section, or uterine rupture. A few maternal, fetal, and neonatal deaths have been reported because of oxytocin errors.

Since the mid-1990s, ISMP has been publishing safety alerts related to errors with oxytocin use. In February 2020, ISMP analyzed voluntary error reports submitted to the ***ISMP National Medication Errors Reporting Program*** *(ISMP MERP)* between 1999 and 2019. During that time, 52 reports involved oxytocin. About 10% of the reports described more than one oxytocin error that had occurred. About 44% of the reported events originated during dispensing, about a quarter (23%) originated during administration, and 13% during prescribing. A quarter (25%) of all events resulted in maternal, fetal, or neonatal harm. Analysis of these reports identified five event themes: prescribing errors, look-alike drug packaging and names, preparation challenges, administration-associated errors, and communication gaps; therefore, a *Best Practice* recommendation has been created for each of these five event themes.

Best Practice 17 First Introduced:
2022-2023

Related *ISMP Medication Safety Alerts!*:

January 28, 2021; November 5, 2020; **February 13, 2020**; January 30, 2020; July 26, 2018; April 19, 2018; August 9, 2012; September 9, 2010; June 3, 2010; June 18, 2009; September 11, 2008; June 15, 2006; March 23, 2006; November 3, 2005; October 20, 2005; July 14, 1999; June 30, 1999.

NEW Best Practice

NEW BEST PRACTICE 19:

Layer numerous strategies throughout the medication-use process to improve safety with high-alert medications.

a) For each medication on the facility's high-alert medication list, outline a robust set of processes for managing risk, impacting as many steps of the medication-use process as feasible.

b) Ensure that the strategies address system vulnerabilities in each stage of the medication-use process (i.e., prescribing, dispensing, administering, and monitoring) and apply to prescribers, pharmacists, nurses, and other practitioners involved in the medication-use process.

c) Avoid reliance on low-leverage risk-reduction strategies (e.g., applying high-alert medication labels on pharmacy storage bins, providing education) to prevent errors, and instead bundle these with mid- and high-leverage strategies.

d) Limit the use of independent double checks to select high-alert medications with the greatest risk for error within the organization. (e.g., chemotherapy, opioid infusions, intravenous [IV] insulin, heparin infusions).

e) Regularly assess for risk in the systems and practices used to support the safe use of medications by using information from internal and external sources (e.g., The Joint Commission, ISMP).

f) Establish outcome and process measures to monitor safety and routinely collect data to determine the effectiveness of risk-reduction strategies.

Rationale:

Events continue to happen in hospitals with medications that are on the hospital's list of high-alert medications. High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients. This is repeatedly borne out in the literature and by reports submitted to the ***ISMP National Medication Errors Reporting Program*** *(ISMP MERP)*. High-alert medications top the list of drugs involved in moderate to severe patient outcomes when an error happens. Most facilities have defined a list of high-alert medications, but some hospitals have neither a well-reasoned list of high-alert medications nor a robust set of processes for managing the high-alert medications on their list. Organizations' attempts to prevent errors may be limited to low-leverage risk-reduction strategies, rely on staff vigilance to keep patients safe, or focus on a single step or single practitioner in the medication-use process. The goal of this *Best Practice* is to engage hospitals to reassess their current list of high-alert medications, enact robust error-prevention strategies throughout the medication-use process, and monitor outcomes to reduce the risk of harm with these drugs.

Best Practice 19 First Introduced:
2022-2023

Related *ISMP Medication Safety Alerts!*:

June 4; 2020; June 6; 2019; August 23; 2018; October 23; 2014; September 19; 2013; September 5; 2013; **April 4; 2013**; April 8; 2010; January 11; 2007

ISMP
Institute for Safe Medication Practices
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ALERTS ABOUT CONTACT NEWS

Information for consumers

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- Perioperative Settings
- Sterile Compounding
- Best Practices for Hospitals
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Self Assessments
- Perioperative Settings
- High-Alert Medications
- Community/Ambulatory
- See More...

Recommendations
- Error-Prone Abbreviations
- Confused Drug Names
- Do Not Crush
- See More...

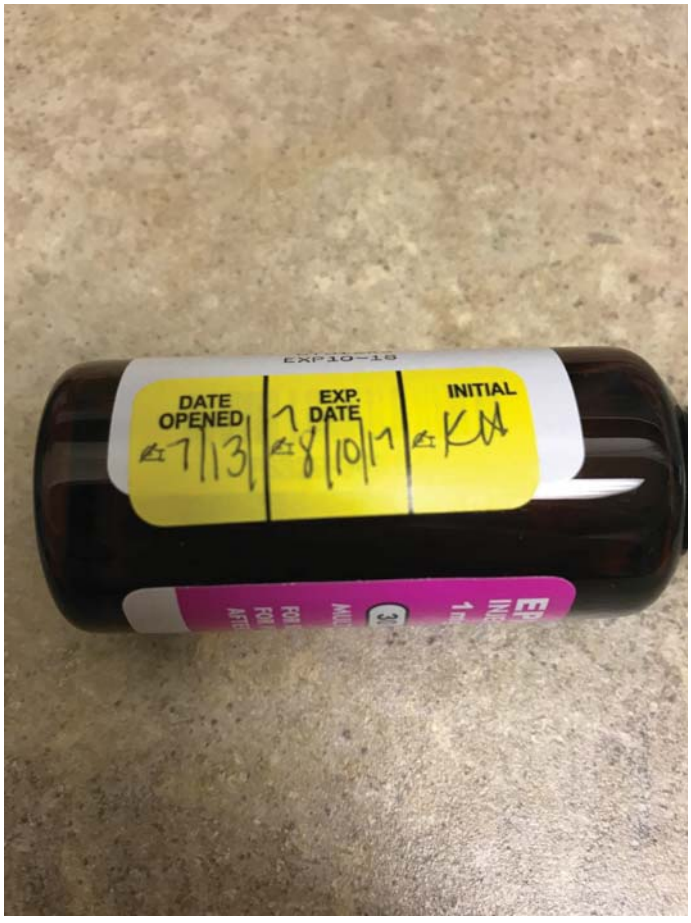
Tools
- IV Push Gap Analysis Tool
- Preparing Student Nurses
- Consumer Learning Guides
- See more...

Reports
- Vaccine Bi-Annual Report

https://www.ismp.org/resources?field_resource_type_target_id%5B13%5D=13#resources--resources_list

Best Practice or Bad Practice?

Best Practice or Bad Practice?



Best Practice or Bad Practice?

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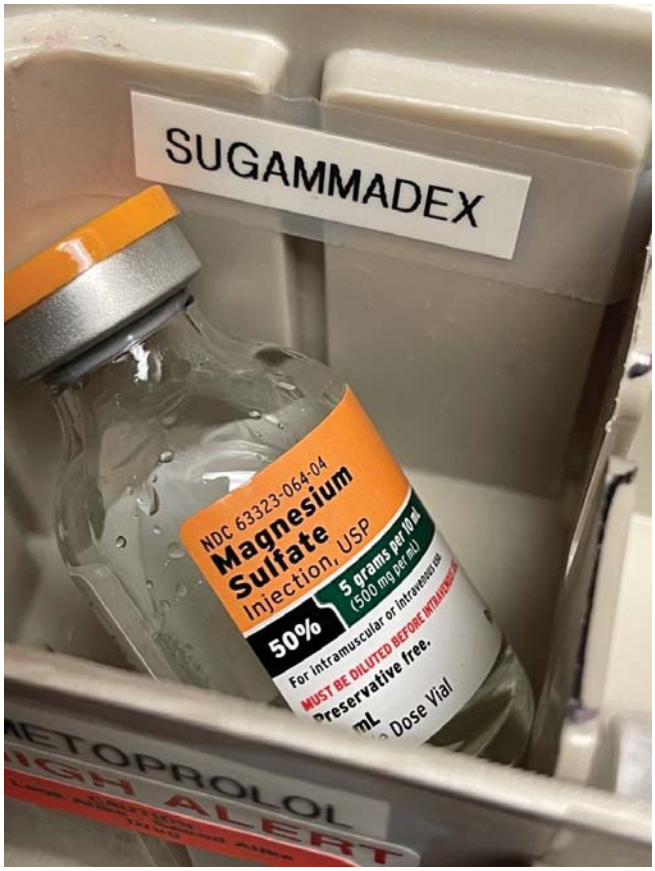
Best Practice or Bad Practice?



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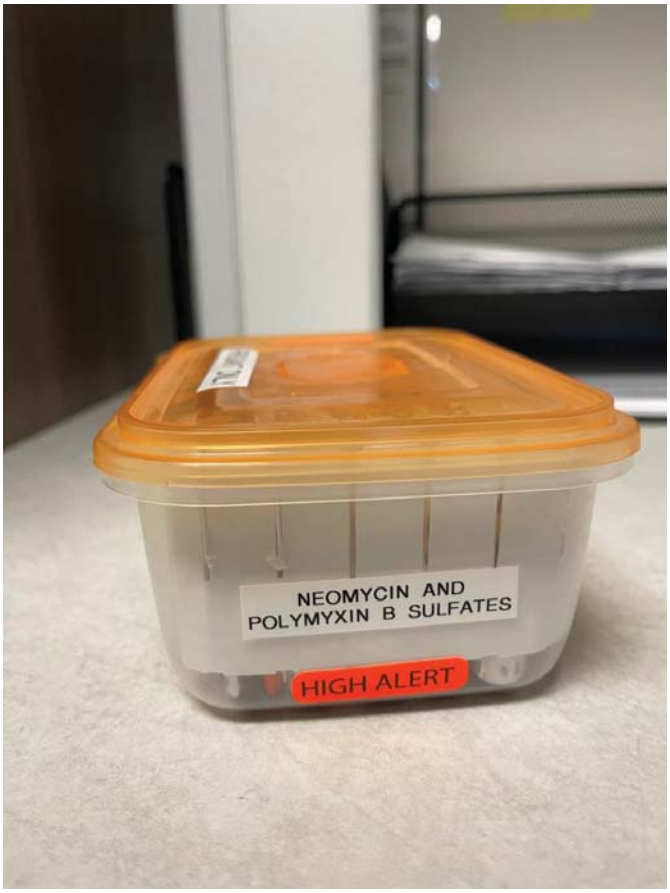
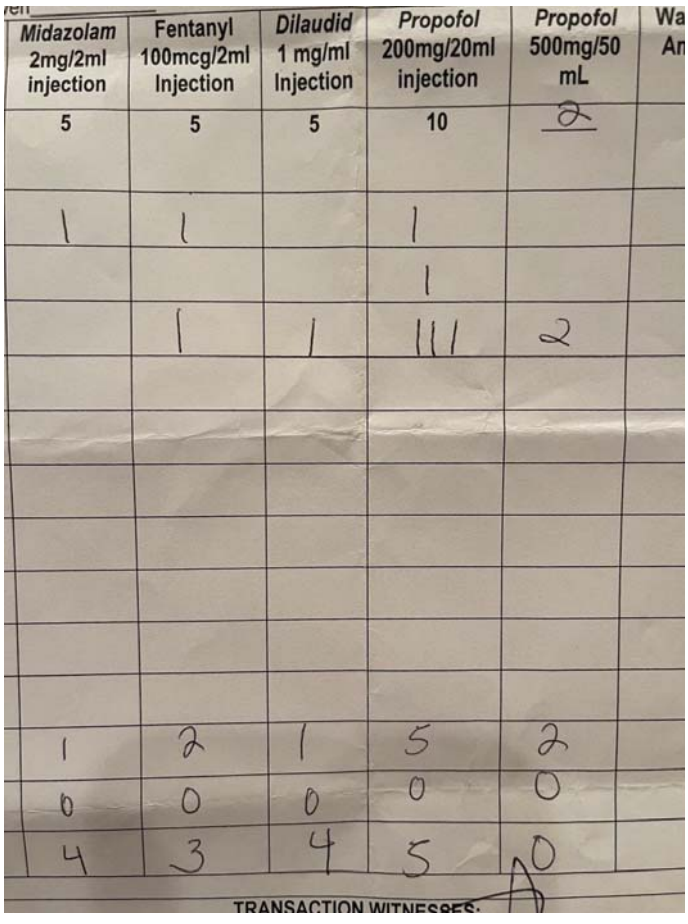
Best Practice or Bad Practice?





Midazolam 2mg/2ml injection	Fentanyl 100mcg/2ml Injection	Dilaudid 1 mg/ml Injection	Propofol 200mg/20ml injection	Propofol 500mg/50 mL	Wa An
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TRANSACTION WITNESSES:

Best Practice or Bad Practice?

Best Practice or Bad Practice?

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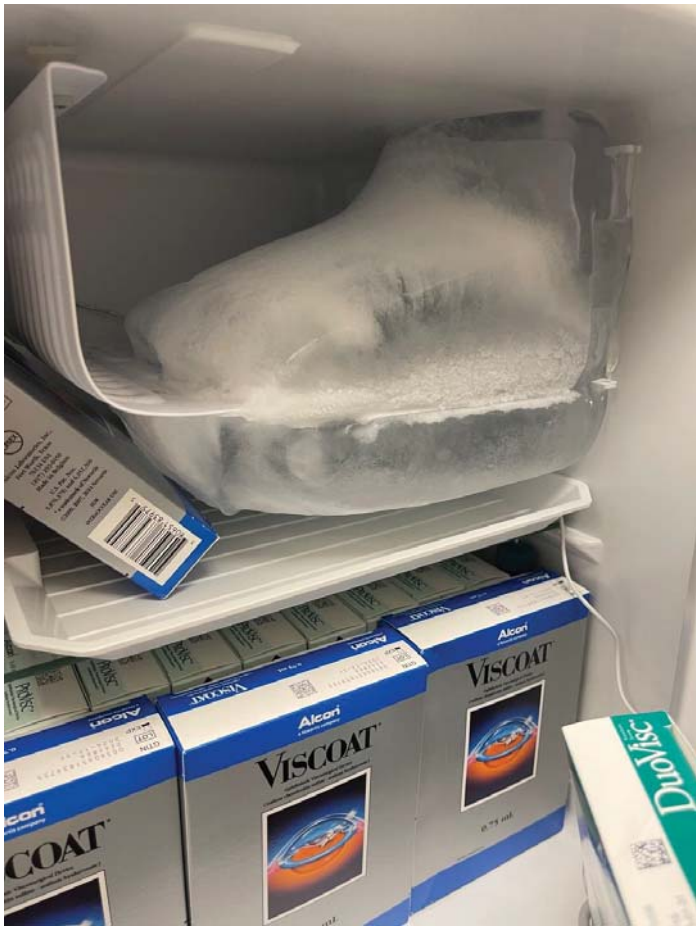

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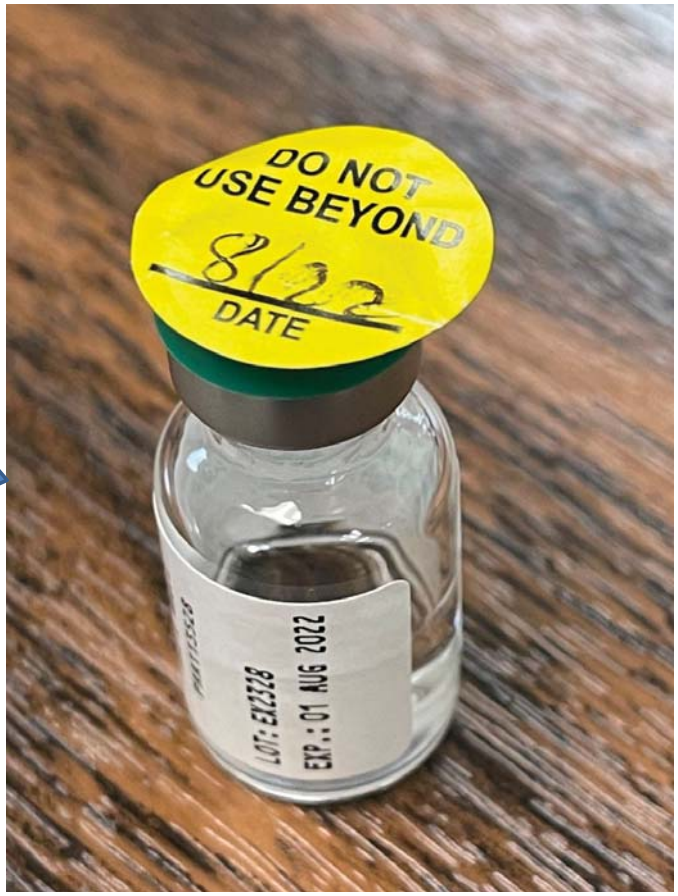
Best Practice or Bad Practice?



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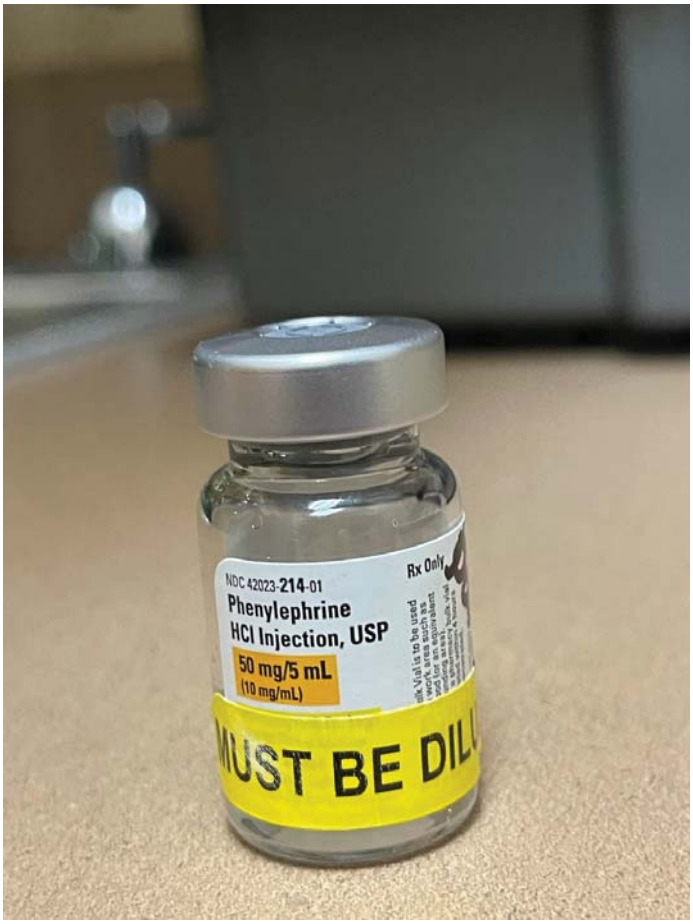

Best Practice or Bad Practice?

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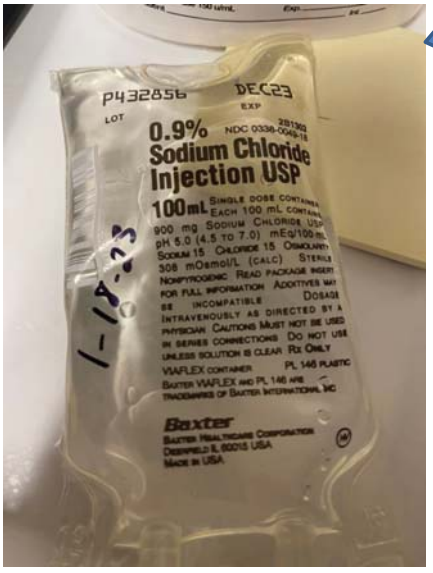
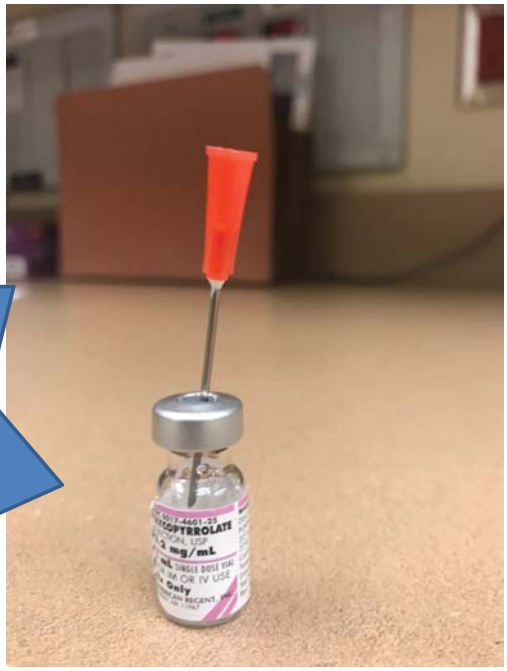
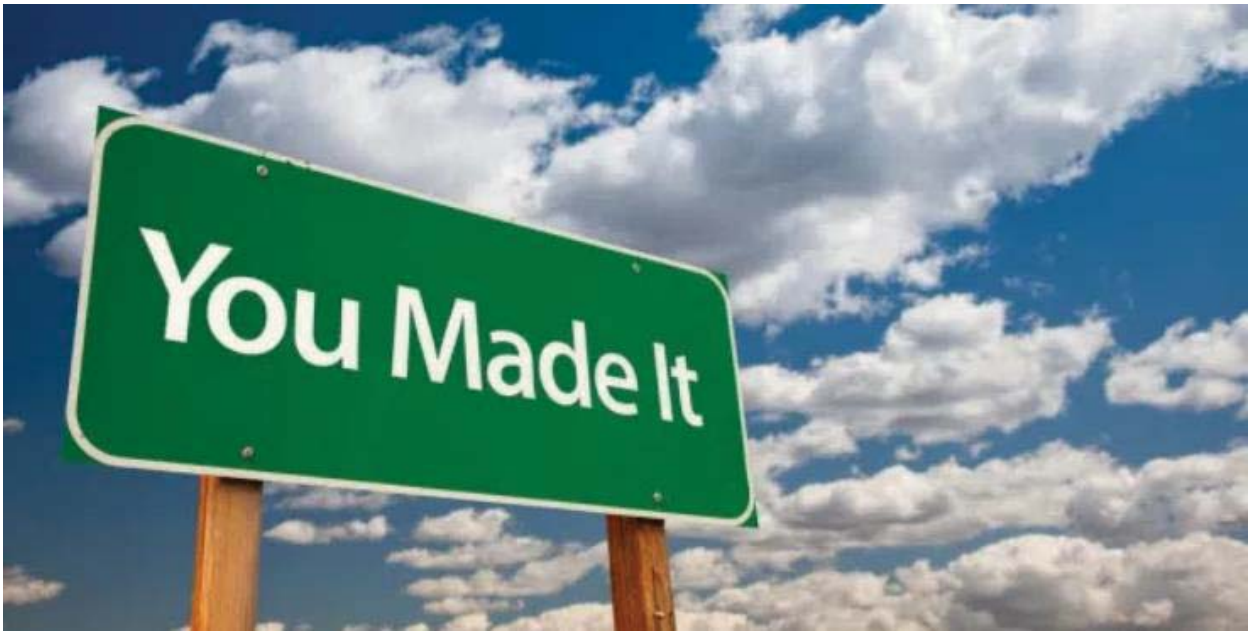


Best Practice or? Bad Practice





"ONE PERSON CAN MAKE A DIFFERENCE, AND EVERYONE SHOULD TRY."

– JOHN F. KENNEDY

Q/A : Open Discussion

michaeloneal01@comcast.net

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