



PHARMACY UPDATES

FEATURING THE
MOUTH OF THE SOUTH

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ABOUT US

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THANK YOU TO
THE NJAASC
BOARD



RECEIVED A COMPLIMENT...



- “You are like a state survey, but nicer.”

USP-797

STERILE PREPARATIONS

A BRIEF UPDATE

THE USP DEFINES STERILE COMPOUNDING MORE AS, “COMBINING, ADMIXING, DILUTING, POOLING, RECONSTITUTING, REPACKAGING, OR OTHERWISE ALTERING A DRUG OR BULK DRUG SUBSTANCE TO CREATE A STERILE MEDICATION”

SPIKING IV BAGS

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.

SPIKING IV BAGS

The old version of USP-797, interpreted spiking to be inclusive of the preparation of sterile I.V. solutions.

→ The Joint Commission mandated that I.V. fluid bags be used within one hour of spiking because of perceived bacterial contamination risks, sparking clinical and economic concerns.

→ Multiple studies were conducted, which resulted in no bacterial growth for various times (1, 2, 4, 8 hours... all the way to 9 days).

→ But what next from JCAHO?

JCAHO RESPONSE

- The Joint Commission will survey to organization's policies and procedures regarding the pre-spiking of IV bags.
- Organization policies, procedures, staff education/competencies, etc., should also take into account:
 - Product and device manufacturer's instructions for use
 - Evidence-based guidelines for safe administration practices
 - Applicable law and regulation

IDEAS?

- American Society of Anesthesiologists, “... intravenous (IV) fluid bags may be safely connected to tubing and prepared (“spiked”), and then used within 24 hours without presenting any substantial risk of infection or contamination...”
- Have you updated your policy?

WHO WANTS TO MAKE JEFF BEZOS EVEN RICHER? TWO QUESTIONS – YOU MAKE THE CALL?

Whoever 1st texts the
correct answer to

**908 – 334 –
5437**



Question on the right and on the left.

I recommend you answer 1 (one) question only.

908 334 5437



CHOOSE WHICH QUESTION TO ANSWER?

TEXT (908) 334 – 5437

\$25 PRIZE

TIN OF CALORIES (X2)

**Based off the information in this picture.
How long are these IV bags good?**

**Who won the College football
championship on Jan 8, 2024**



2. MICHIGAN I'M SORRY OHIO.



QUESTION I

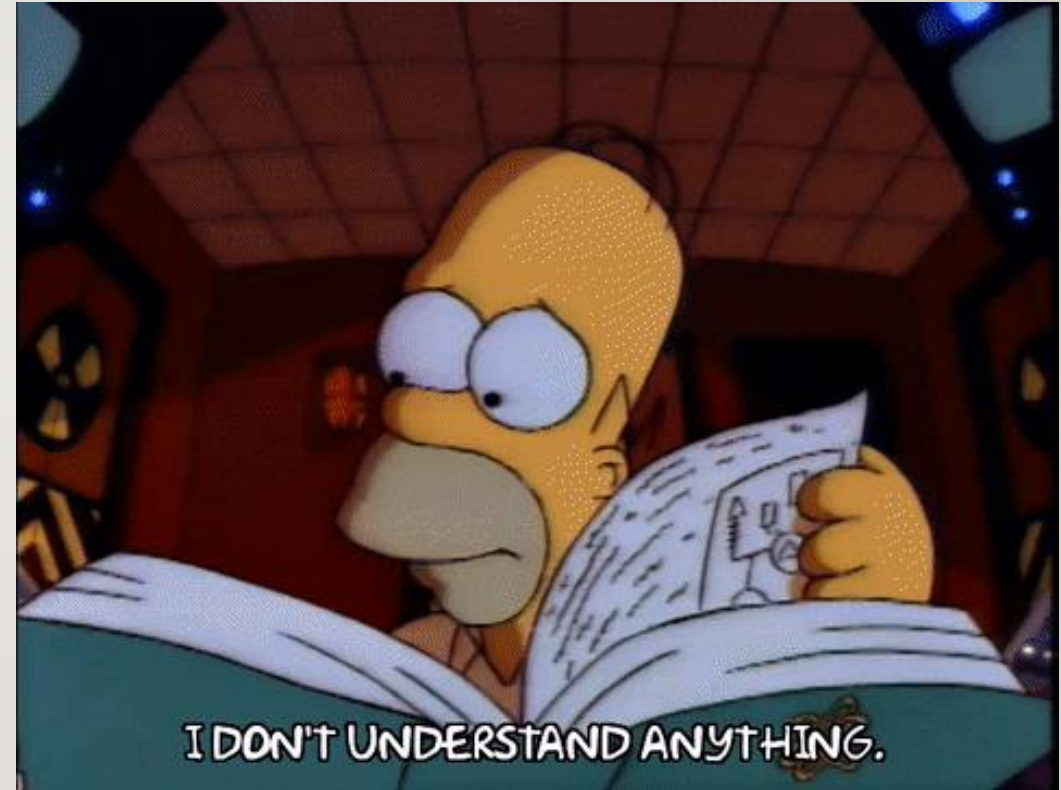
WHERE IS THE LABELING?

- 1, 2, 4, 24 HOURS – it does not matter if there is no label on the IV bag.
- A label with the appropriate information must be present to say when the bag was day, time initially spiked, contents, etc.
- No matter what you change your policy labeling will be required.



DEA FORM 106

IT'S SO CONFUSING



WHEN AND WHY

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.

Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL No. 1517-0001

1. Name and Address of Registrant (include ZIP Code) ZIP CODE 2. Phone No. (include Area Code)

3. DEA Registration Number 7 (last 7 digits) 4. Date of Theft or Loss 5. Principal Business of Registrant (Check one)

1 Pharmacy 5 Distributor
2 Practitioner 6 Methadone Program
3 Manufacturer 7 Other (Specify)
4 Hospital/Clinic

6. County in which Registrant is located 7. Was Theft reported to Police? Yes No 8. Name and Telephone Number of Police Department (include Area Code)

9. Number of Theft or Losses Registrant has experienced in the past 24 months 10. Type of Theft or Loss (Check one and complete items below as appropriate)

1 Night break-in 3 Employee pilferage 5 Other (Explain)
2 Armed robbery 4 Customer theft 6 Lost in transit (Complete item 13)

11. If Armed Robbery, was anyone:
Killed? No Yes (How many) _____
Injured? No Yes (How many) _____

12. Purchase type to registrant of Controlled Substances taken? \$ _____ 13. Were any pharmaceuticals or merchandise taken? No Yes (Est. Value) \$ _____

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier B. Name of Consignee C. Consignee's DEA Registration Number

D. Was the carton received by the customer? Yes No E. If received, did it appear to be tampered with? Yes No F. Have you experienced losses in transit from this same carrier in the past? No Yes (How Many) _____

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513); PURPOSE: Report theft or loss of Controlled Substances. ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purpose stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 802 and 803 of the Controlled Substances Act.

FORM DEA - 106 (11-00) Previous editions obsolete

CONTINUE ON REVERSE

- Upon discovery of a theft or significant loss of controlled substances.
- Must report the loss in writing to the area Drug Enforcement Administration (DEA) field office on DEA Form 106 either electronically or manually within one business day.

SIGNIFICANT LOSS? UPON DISCOVERY?

- All theft must be reported.
- Witnessed breakage or spillage does not constitute a loss of controlled substances, because the loss can be accounted.
- As this may be a recurring trend, we recommend an incident report to see if this is a one-time thing or a trend.
- Within 24 hours of discovery
- As more information is uncovered, the DEA may require more information for up to 2 months.
- Updates must be in writing either electronically or manually.

FACTORS TO CONSIDER...

- 1) The actual quantity of controlled substances lost in relation to the type of business;
- 2) The specific controlled substances lost;
- 3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- 4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- 5) Whether the specific controlled substances are likely candidates for diversion; and
- 6) Local trends and other indicators of the diversion potential of the missing controlled substance.**

ANESTHESIOLOGIST BRINGING IN THEIR OWN MEDS?



WHAT WE FOUND



1. Box left on top of med cart (MD gone)
2. Red arrows – used SDV
3. Talking cloud – Vasostrict, Rocuronium
4. Orange and Teal caps (CDS)
5. Plastic bags of meds
6. Succinylcholine – removed from picture
7. Expired medications from 4-2019

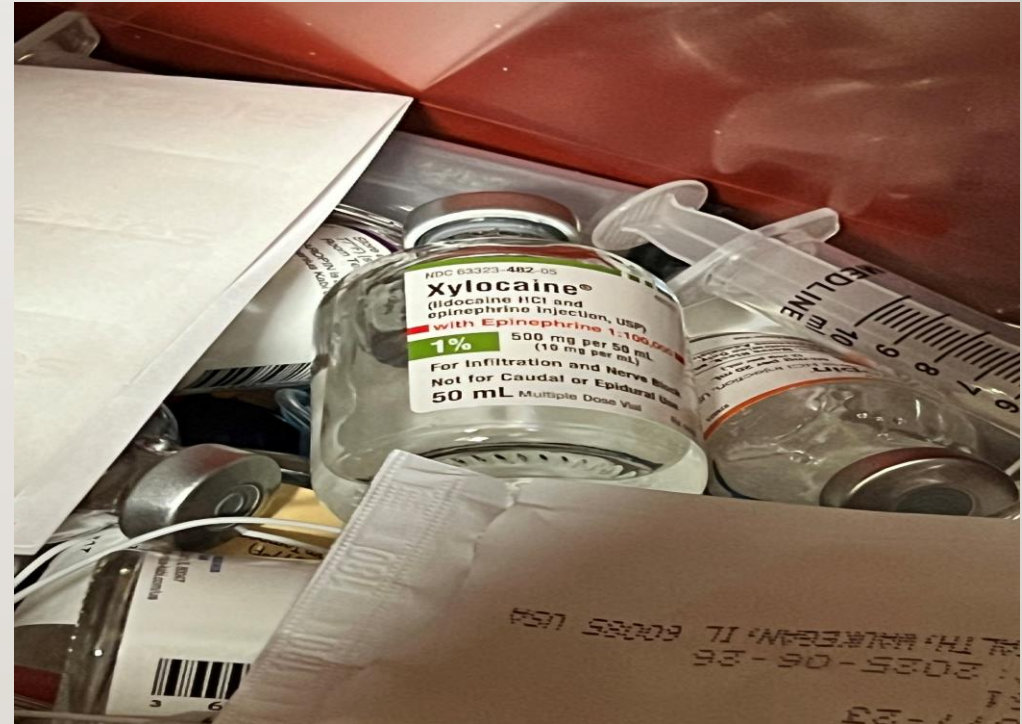
HOW ABOUT THESE GUYS



- What is a single-dose or single-use vial?
 - A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case, procedure, injection.
 - Common for Labetalol, Esmolol
- Problem was it was found after a case.

MEDICATIONS IN THE SHARPS CONTAINER

- Items contaminated with possible bloodborne pathogens or infectious agents are the only items that are supposed to go in regulated medical waste (red) sharps, which means no expired medicines and no pharmaceuticals of any kind.
 - Black sharps
 - Drug Buster/RxDestroyer



YOU HAVE HEARD OF ELF ON THE SHELF BUT HOW ABOUT SPOON IN THE ROOM?!

“The path of least resistance is what makes rivers run crooked.” Elbert Hubbard

- When you see something wrong, say it.
- It is a team effort, only if we work together can we make a difference.

REFERENCES

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5. [https://www.dea diversion.usdoj.gov/GDP/\(DEA-DC-051\)\(EO-DEA144\)Spilled_Methadone_Guidance_Final.pdf](https://www.dea diversion.usdoj.gov/GDP/(DEA-DC-051)(EO-DEA144)Spilled_Methadone_Guidance_Final.pdf)