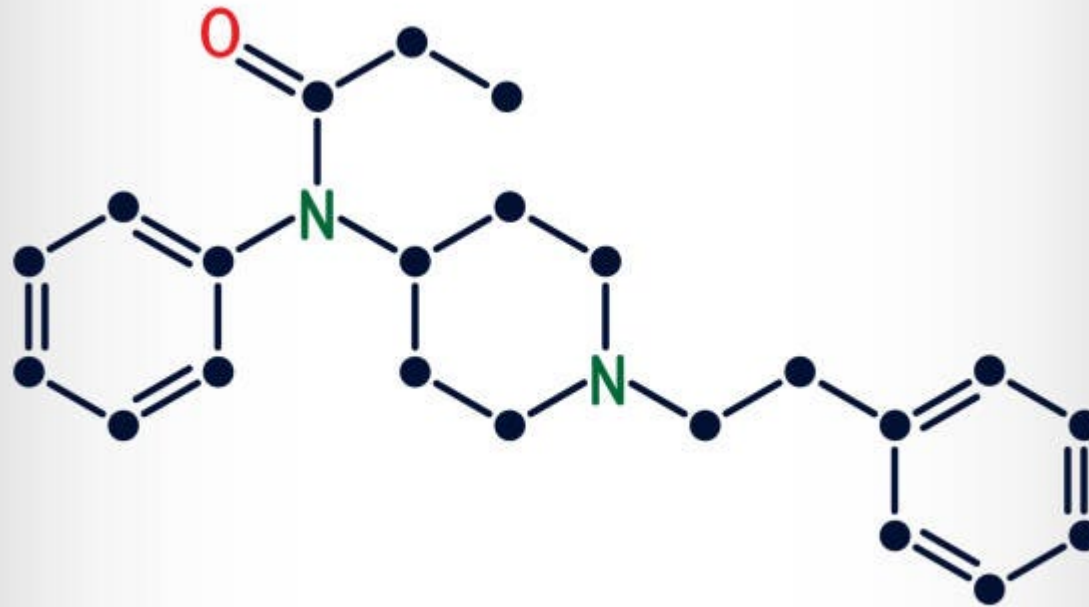


NARCOTIC DIVERSION AND COMPLIANCE



Fentanyl

NARCOTIC DIVERSION AND COMPLIANCE

- Christopher M. Dembny R.Ph.
 - President
- Dembny Pharmacy Consultants LLC

BIOGRAPHY

- Christopher M. Dembny R.Ph.
- Licensed pharmacist in Texas for 40+ years
- Consultant pharmacist for surgery centers for 32 years
- Currently consulting for >150 ASCs
- Board Member – Texas State Board of Pharmacy 2013-2018

FORMAT

- Open format
- Interactive – please ask questions
- My pharmacists and I are around for the entire conference ** L&T

INTRODUCTION

- Who is expecting diversion at their ASC?
- Have you heard of the opioid crisis?
- 16% of the population has a substance abuse problem. (American Addiction Center-2023)

INTRODUCTION

- Why are ASCs great targets for diversion?
- Smaller – fewer people watching
- Fewer “big hospital” safeguards and policies
- Rarely use automation – Pyxis - Omnicell
- Often use paper documentation -Easier to falsify
- Less oversight

INTRODUCTION

- Why are ASCs great targets for diversion?
- Limited pharmacist oversight
- Staff often controls ordering/receiving
- No security/drug diversion officer(s)
- **Diversers choose to work at ASCs for these reasons!**

CONTROLLED SUBSTANCE REQUIREMENTS

- [illegible]

CONTROLLED SUBSTANCE REQUIREMENTS

- (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).

CONTROLLED SUBSTANCE REQUIREMENTS

- CII invoices and DEA222 forms (e222)
- i. **must be filed separately from other documents.**
- ii. DEA222 must be completed with number of packages received and date received. (e222)
- iii. Invoices and 222 must be signed by person receiving drugs and pharmacist.

CONTROLLED SUBSTANCE REQUIREMENTS

- CIII-V invoices must be filed separately from other documents.
- I recommend getting a monthly summary of all controlled substances sent from your wholesaler so that you can verify that you have received and have added to inventory all controlled substances that the wholesalers have sent to you. This will also validate that you have all invoices that you are responsible for on file*****

CONTROLLED SUBSTANCE REQUIREMENTS

- Reproducible audit trail for each dosage unit.
 - i. patient administrations
 - ii. transfer to another registrant
 - iii. documentation of waste (of broken vials)
 - iv. transfer to reverse management company for destruction.
 - Do not destroy expired controlled substances. *
 - v. report of theft or loss.

CONTROLLED SUBSTANCE REQUIREMENTS

- Controlled substance administration records
 - Date and time of administration **
 - Patient name
 - Drug and dose administered
 - Signature of person administering **
 - Waste and signature of person witnessing waste (if any)
 - Ordering practitioner

Must be maintained separately from chart ???

METHODS OF DIVERSION ORDERING AND RECEIVING

- Ordered CS and don't receive/add to stock
- My worst diversion in 25 years
- 2600 tablets of Ambien
- Director of Nursing - Good friend
- Ordered and received drugs *****TSBP
- **** Different people should order and receive CS**

METHODS OF DIVERSION ORDERING AND RECEIVING

- Shipment stolen after delivery
- Delivered by UPS
- Signed for at front desk
- Disappeared before it was locked in pharmacy
- Large diversion of full packages
- **** Immediately secure delivered CS**

METHODS OF DIVERSION ORDERING AND RECEIVING

- Stolen in transit
- UPS package lost
- Stolen from delivery box on the counter in PACU
- Delivered, opened but not secured. MS 50mg/ml 100ml bag for pain pump.
- **** Different people should order and receive CS**

METHODS OF DIVERSION TAMPERING

- Save used ampoules for breakage
- Save ampoules and tray
- Sprinkle inside with water
- Trade out used for good amps
- Publicly drop and BREAK amps in tray ****47 amps****
- **** be suspicious of large scale/frequent waste**

METHODS OF DIVERSION TAMPERING

- Open boxes from back or underneath
- Seal and replace
- Place on the bottom in the rear
- Remove, refill, and superglue ampoules
- Yes, it is possible - Hep B ****
- ** **Do a careful count once a week**

METHODS OF DIVERSION TAMPERING

- Pop tops off FTV, remove and reglue
- Glue is usually evident
- **Caps no longer spin!**
- Dermabond works great except for the purple residue.
- Caps can be recrimped but I've never seen it.
- **** Do a careful count once a week**

METHODS OF DIVERSION TAMPERING

- Replace UD tabs with other similar looking drugs
- If you don't examine the packaging closely, you won't realize for a while.
- Following picture contains 20 acetaminophen tabs.
- **** Do a careful count once a week**

METHODS OF DIVERSION



METHODS OF DIVERSION

FALSE DOCUMENTATION

- Made up orders written in PACU chart
- Made up admin records – Late entries
- Sign out drugs to anesthesia
- Don't give them to anesthesia
- **** Reconcile removal and charts**

METHODS OF DIVERSION FALSE DOCUMENTATION

- Alter Anesthesia record
- Sign out drug to anesthesia
- Add drug to anesthesia CSAR
- Had clean urine in lunch bag in refrigerator
- Anesthesia couldn't tell it wasn't his writing ****
- ** **Reconcile removal and charts**

METHODS OF DIVERSION

FALSE DOCUMENTATION

- Extra drawn up to waste (fent-midaz)GI ****
- Multiple vials
- 125 mcg dose of fentanyl
- 12mg dose of morphine
- Lots of waste
- ** **Watch for excess wastage**

METHODS OF DIVERSION THEFT

- Last nurse on shift cleaned out
- EVERYTHING
- Didn't take long to determine who it was
- All controlled substances stolen
- **** Secure bulk storage?**

METHODS OF DIVERSION THEFT

- Steal from anesthesia box between cases
- **Must secure anesthesia CS between cases.**
- Steal Ativan injectable from refrigerator
- **Make sure to actually count refrigerated items**

METHODS OF DIVERSION THEFT

- Facilities maintenance guy
 - Really?
 - Great story and movie *****
-
- **Cameras on the Controlled substance box.**

Strategies for Prevention

- #1 ***** Think like a criminal
 - #2 Keep your eyes open
 - #3 Adequate security
-
- Is this adequate security?
 - Only one lock?

Strategies for Prevention



Strategies for Prevention

Physical

- Badge Access or Bio ID is IDEAL
- Review badge/bio access log
- Review badge/bio access list
- KEEP LOCKED DOORS CLOSED!!!

Strategies for Prevention

Physical

- Punch lock
- Does everyone have their own code?
- Can we retrieve entry log?
- Can we review active codes – who can access
- Review periodically

Strategies for Prevention

Physical

- Automated dispensing units (ADU) create great audit trails
- Pyxis, Omnicell, others
- REVIEW the reports
- Reconcile invoices and add to stocks - transfers
- Reconcile some administrations
- Someone must load/maintain system.

Strategies for Prevention

Physical

- Cameras
- Cameras should view into storage area when open
- Tape should be saved for 2 weeks or so

Strategies for Prevention Policy

- Different person orders from the person who receives controlled substances
- Don't give others badge/code
- Don't allow non-licensed persons access
- Temps-prn access?
- Drug deliveries are immediately secured

Strategies for Prevention Policy

- **MOST IMPORTANT ITEM**
- **Get a monthly summary from your drug wholesaler of all controlled substances shipped to your site.**
- **Reconcile to make sure that everything on that report is added to your inventory!!!!**

Strategies for Prevention Policy

- Count controlled substances start/end of day
- Different people count/record
- CAREFUL count once a week
- When daily count is done - COUNT
- .

Conclusion

- People steal drugs
- It's our job to
 - A. Stop it
 - B. Decrease it
 - C. Identify it when it happens and take action to prevent a recurrence.

QUESTIONS

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Thank you
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