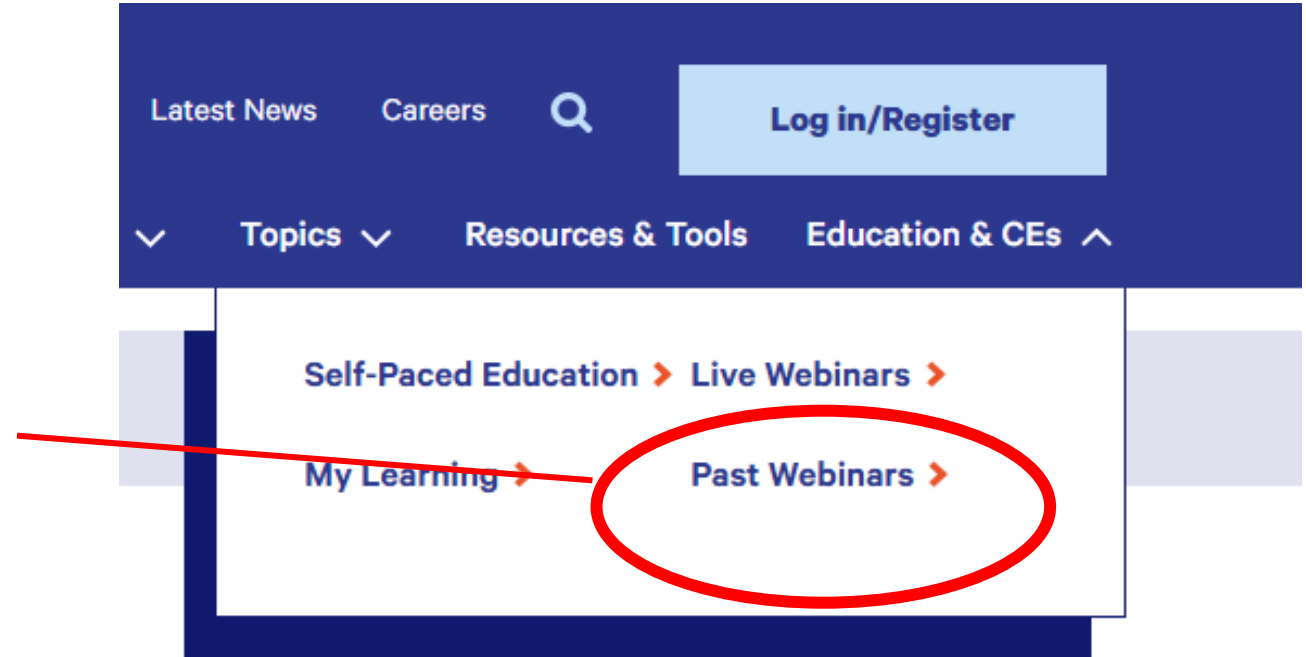


Navigating DEA Compliance: Expert Tips for Managing Medications in Dental Settings

March 13, 2025

Webinar Guidelines

- All lines will be muted to avoid background noise.
- Today's presentation and slides will be available on our website at **carequest.org** under the **"Education" tab** and **"Past Webinars"**, within the next two business days.



The CareQuest Institute for Oral Health is an ADA CERP Recognized Provider. This presentation has been planned and implemented in accordance with the standards of the ADA CERP.

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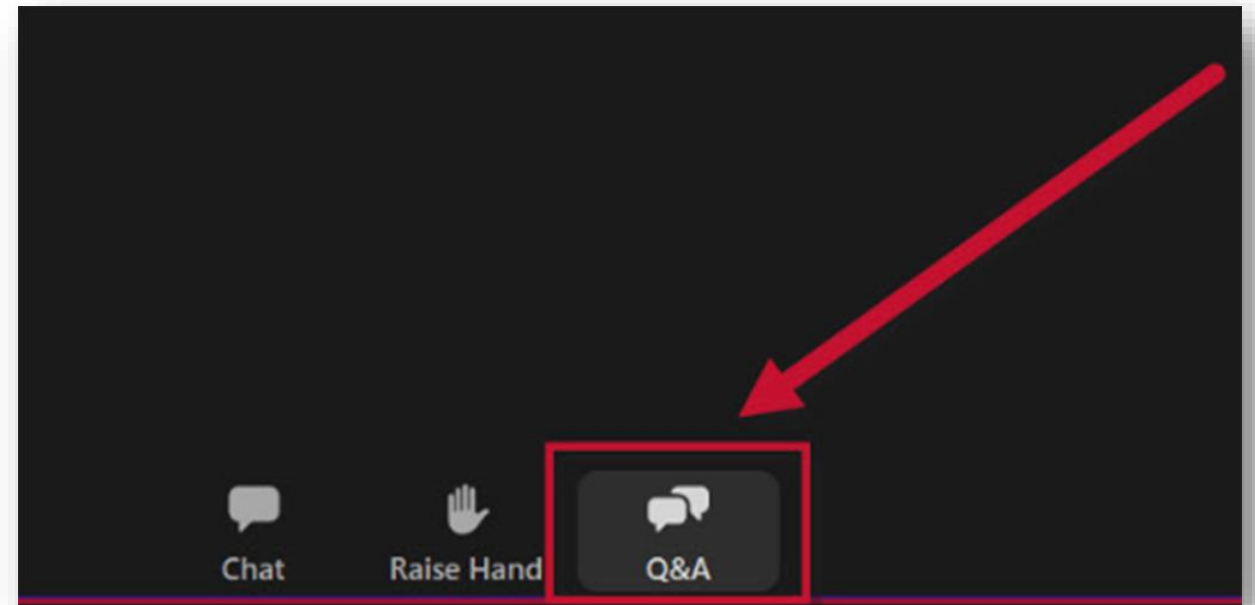
Complete the evaluation by Friday, March 21.

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Question & Answer Logistics

- Feel free to enter your questions into the **Question & Answer box** throughout the presentations.
- We will turn to your questions and comments toward the end of the hour.



Webinar

Navigating DEA Compliance:

Expert Tips for
Managing Medications
in Dental Settings

Thursday, March 13, 2025
7-8 p.m. ET

ADA CERP Credits: 1



Moderator

Niketa G. Prince

Diversion Staff Coordinator,
Liaison Section,
Diversion Control Division,
Drug Enforcement Administration



Presenter

Jennifer Reed

Diversion Staff Coordinator,
Liaison Section,
Diversion Control Division,
Drug Enforcement Administration

Learning Objectives

- Identify key Drug Enforcement Administration (DEA) requirements for inventory management, storage, and recordkeeping of controlled substances in dental offices.
- Describe strategies for implementing secure and compliant inventory management and storage systems.
- Analyze real-world compliance failures and successes to understand their causes and consequences.

Poll Questions

1. In your experience, what do you think is the most common controlled substances DEA compliance risk?

- Inventory management
- Storage regulations
- Recordkeeping
- All of the above

2. How familiar are you with DEA requirements for managing controlled substances in a dental setting?

- Very familiar
- Somewhat familiar
- Somewhat unfamiliar
- Very unfamiliar

Webinar

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Preparing for a DEA Inspection: What to Expect and How to Better Prevent Diversion



Jennifer Reed
Diversion Staff Coordinator
Liaison Section
Diversion Control Division

March 13, 2025

Hosted by: **CareQuest** 
Institute for Oral Health.

Legal Disclaimer



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TODAY'S PLAN



- Understanding diversion:
 - basic terminology
 - regulations related to diversion
- What to expect during a DEA inspection
- Review case studies to explore diversion opportunities
- Learn what you can do to:
 - Better prevent diversion
 - Better detect diversion
 - Keep patients, staff, and the community safe
 - Decrease your liability



Diversion Control Division



To prevent, detect, and investigate the diversion of controlled substances & listed chemicals from legitimate sources



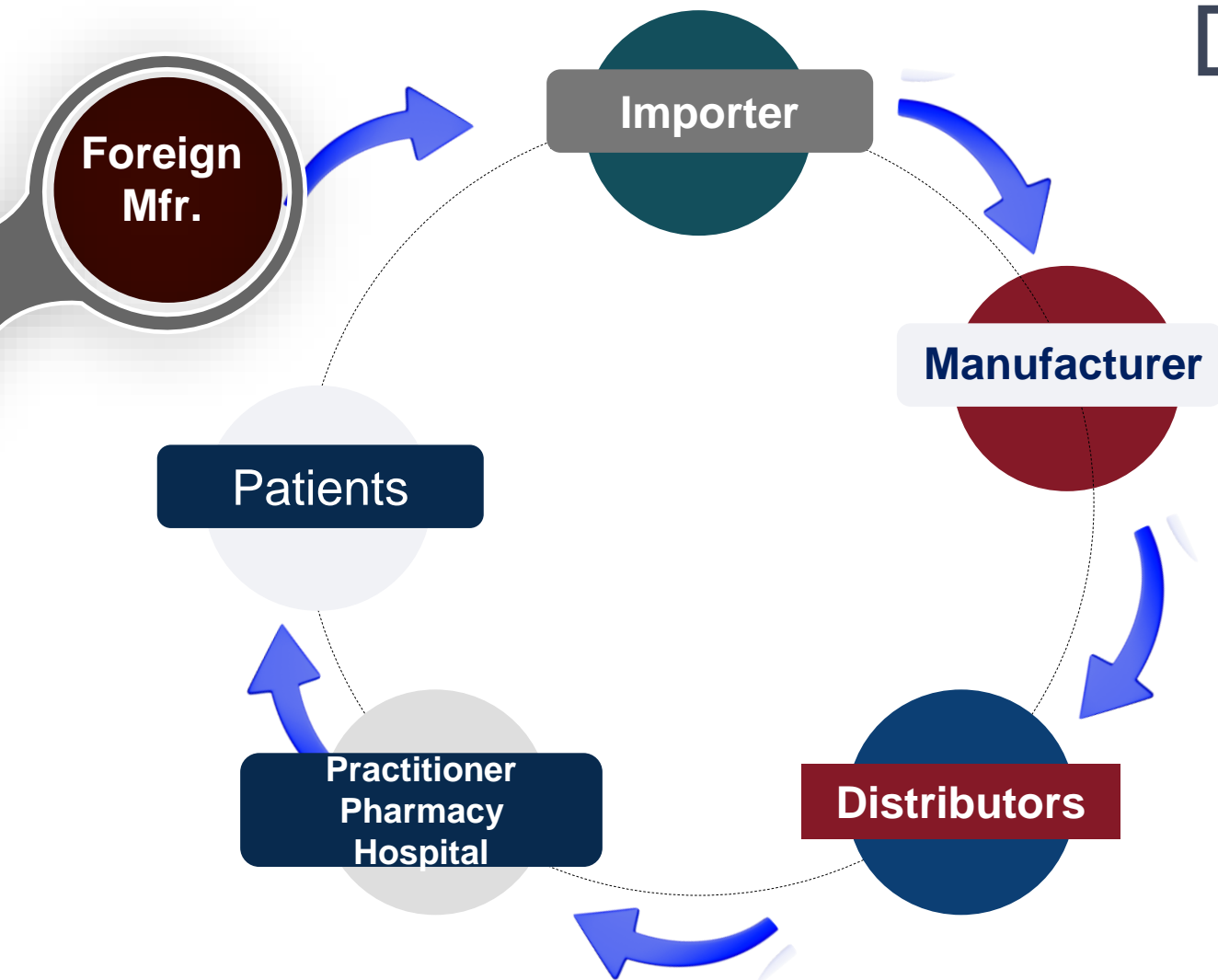
while



Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes.



Closed System of Distribution

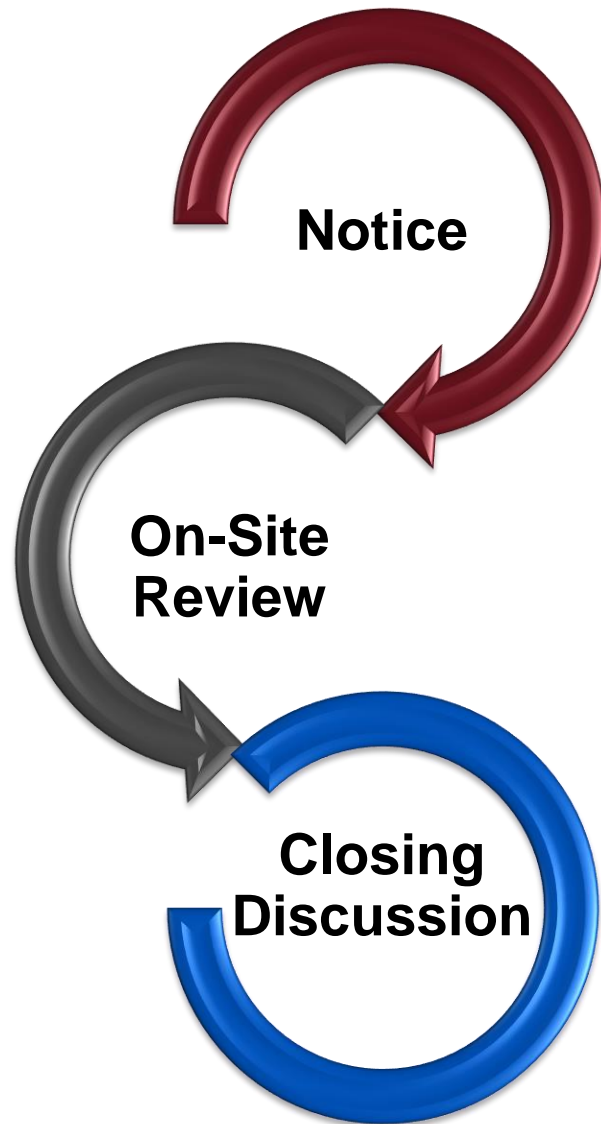


DEA is responsible for:

- oversight of the system
- integrity of the system
- protection of the public health and safety

Oversight of Closed System of Distribution





Types

- (1) Regulatory
- (2) Complaint
- (3) Criminal





Primary purpose of the inspection is to ensure compliance with Controlled Substances Act





DEA On-site Investigation

What to expect:

- Present Credentials
- Ask to sign DEA-82, Notice of Inspection



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

**NOTICE OF INSPECTION
OF CONTROLLED PREMISES**

DEA USE ONLY

FILE NUMBER

NAME OF INDIVIDUAL		TITLE
NAME OF CONTROLLED PREMISES		DEA REGISTRATION NO.
NUMBER AND STREET		DATE
CITY AND STATE	ZIP CODE	TIME (<i>initial inspection</i>)

STATEMENT OF RIGHTS

1. You have a constitutional right not to have an administrative inspection made without an administrative inspection warrant.
2. You have the right to refuse to consent to this inspection.
3. Anything of an incriminating nature which may be found may be seized and used against you in a criminal prosecution.
4. You shall be presented with a copy of this Notice of Inspection.
5. You may withdraw your consent at any time during the course of the inspection.



Steps of an On-Site Inspection



- Meet with Registrant and controlled substance handler(s)
- Tour of Facility: Specifically, where controlled substances are kept
- Discussions of Standard Operation Procedures (SOPs)
- Controlled substance document request
- Physical count of Controlled Substances on hand



Controlled Substance Inventory



A physical inventory count of **ALL** controlled substances on-hand.

Including:

- Automated Dispensing Machines
- MedCarts
- Safes
- Disposal/Expired



General Recordkeeping Requirements



Must be

Kept for two years.
21 C.F.R. § 1304.04(a)

Complete and accurate.
21 C.F.R. § 1304.21(a)

Stored at the registered location.
21 C.F.R. § 1304.21(b)

Kept for each separate DEA registered activity.
21 C.F.R. § 1304.21(c)

Readily retrievable.
21 C.F.R. § 1304.04(f)(2)

Kept for each DEA registered location.
21 C.F.R. § 1304.21(b)

Separate Records Schedules



Records shall be maintained separately from all other records

**SCHEDULE
II**

Must be kept separate from all other records or readily retrievable. Records that are readily retrievable can be **separated out in a reasonable time.**

Examples of ways to render your **records readily retrievable** include but not limited to:

- Items asterisk
- Redlined
- Or in some manner which sets them visually apart.

**SCHEDULE
III**

**SCHEDULE
IV**

**SCHEDULE
V**





Items Requested During Inspection

- List of Employees with Access to Controlled Substances (Name, Title, Address, DOB, SSN)
- Copies of Licenses and Certificates (state/other federal)
- Facility Floor Plan
- Receiving Records (222s, Invoices/purchase orders/packing slips, CSOS)
- Dispensing/Distribution Records
- Records of Returns (Schedules II-V)
- Records of Destruction (DEA Form-41s, Waste Records, Reverse Distributor)
- Theft/loss reports (DEA Form-106)
- Copy of most recent biennial inventory
- Copy of alarm company contract
- List of Suppliers (Name, address, DEA #)





Accountability Audit

Investigators will:

- Count all controlled substances on hand
- Review all receipts, invoices and dispensing records for the audit period
- Calculate any differences (shortages or overages)
- Verify whether the registrant is maintaining proper records



Controlled Substance Records



- Most recent Biennial Inventory
- Reconciliations
- Receiving Records
 - DEA-222 Forms
 - Invoices
- Distribution Records
 - Dispensing
 - Disposal & destruction Records
 - Theft/Loss Reports





Theft or Significant Loss



Written notification required for a theft or significant loss of any controlled substance within one business day of discovery



Notify local police department



Complete and submit a DEA Form-106 (theft and loss report)

Must be electronically filed

“21 CFR 1301.76 (b)”





Theft or Loss –Two step requirement



Notify local Field Division Office of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss



Submit a “Report of Theft or Loss of Controlled Substances,” DEA Form 106, electronically to the agency within 45 days of discovery of a theft or significant loss **“21 CFR 1301.76 (b)”**





Reporting a Theft or Significant Loss

21 CFR 1301.76
Other security controls for practitioners

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

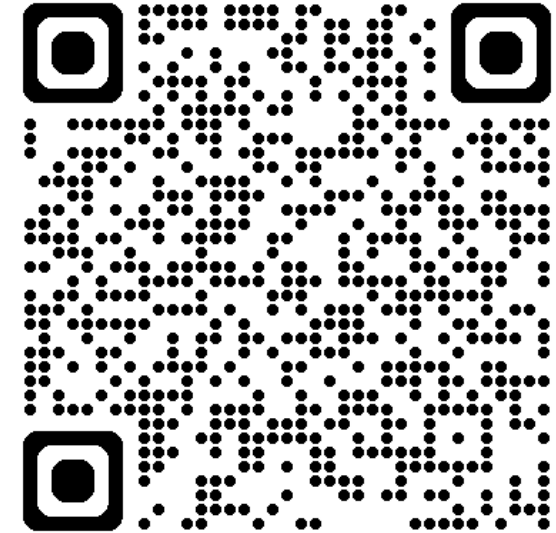
- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) The specific controlled substances lost;
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can 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;
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.



Theft or Significant Loss: DEA-Form 106






REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES		
1. Name and Address of Registrant [REDACTED]		2. Phone No. [REDACTED] Amendment Key / Date Submitted [REDACTED]
3. DEA Registration Number [REDACTED]	4. Date of Theft / Loss 2022-04-27 Amendment # 1 [REDACTED]	5. Registrant's Principal Business [REDACTED]
6. Registrant's County MARICOPA	7. Theft Reported to Police? Y	8. Dent, Name, Report #, Officer Name, and Phone of Police Dept. [REDACTED]
9. Number of Thefts /Losses Registrant Has Experienced in Past 24 Months? 0	10. Type of Theft / Loss Employee Theft (or Suspected)	
11. Killed / Injured Due to Armed Robbery	12. (Purchase) Value of Substances 106/107 \$2 /	13. Pharmaceuticals or Merchandise Taken? N
14. The following applies when Type of Theft / Loss (Box 10) is "Lost In Transit":		
A. Name of Common Carrier	B. Name of Consignee	C. Consignee's DEA Registration Number
D. Did the Customer Receive the Carton?	E. Was Carton Tampered With?	F. Theft or Loss From This Same Carrier in the Past 0
15. What identifying marks, symbols or price codes were on the labels of these containers that would assist in identifying them? TRAMADOL 50MG: WHITE, OVAL-SHAPED, SIDE 1: OUYI, SIDE 2: 101 ALPRAZOLAM 2MG: BLUE, RECTANGULAR-SHAPED, MULTI-SEGMENTED, SIDE: B 7 0 7 ALPRAZOLAM 0.5MG: PEACH, OVAL-SHAPED, SCORED, SIDE 1: GG 257		
16. Numbers of Official Controlled Substances Order Forms (DEA-222)		
17. What security measures have been taken to prevent future theft / loss? 1. WILL REVIEW RX TECHNICIAN QUALIFICATIONS FOR THE CONTROLLED SUBSTANCE CAGE. 2. REVIEW CONTROL CAGE BEST PRACTICES WITH PHARMACIST(S) AND RX TECHNICIANS.		
18. Comments A DISCREPANCY WAS IDENTIFIED DURING A CYCLE COUNT. THIS PROMPTED LOSS PREVENTION TO INITIATE AN INVESTIGATION. FOOTAGE IDENTIFIED A LICENSED PHARMACY TECHNICIAN DIVERTING TRAMADOL 50MG AND ADDITIONAL MEDICATIONS IN THEIR POCKET. INTERVIEWS WERE CONDUCTED WITH THE TECHNICIAN, WHO ATTESTED TO THEFT WITH A VERBAL AND WRITTEN STATEMENT. PHOENIX POLICE DEPARTMENT WAS NOTIFIED AND POLICE REPORT FILED.		
19. Filer Name, Title, Phone: [REDACTED]		





Drug Destruction

-  Use a Reverse Distributor
-  DEA Form 41 Drug Destruction “21 CFR 1317.90”
-  You CANNOT accept “unwanted” drugs from the public (patients)





DISPOSE OF UNNEEDED MEDICATIONS

FREE - ANONYMOUS - SAFE



APRIL 26, 2025

10 AM – 2 PM

FIND A COLLECTION SITE
NEAR YOU:



www.DEATakeBack.com

Every Day is TAKE BACK DAY



CLEAN THEM OUT

TAKE THEM BACK



ALL YEAR LONG



Dispose of unneeded
medication in a
collection site near you



SCAN ME

Disposal of Controlled Substance Inventory



Title 21 Code of Federal Regulations- PART 1317 — DISPOSAL



OPTIONS TO DISPOSE OF

[21 C.F.R. § 1317.05\(a\) and \(b\)](#)

- Prompt on-site destruction if proper method.
- Prompt delivery to a DEA registered reverse distributor by common carrier or reverse distributor pick-up.



RETURNED OR RECALLED

[21 C.F.R. § 1317.05\(a\) and \(b\)](#)

- Prompt delivery by common or contract carrier or pick-up at the registered location by:
 - Registrant from whom it was obtained.
 - Registered manufacturer of the substance.
 - Another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf.



REQUEST ASSISTANCE- SPECIAL AGENT IN CHARGE

[21 C.F.R. § 1317.05\(a\) \(4\)](#)



Records of Destruction

Exception

§1317.95 Destruction procedures.

- Destruction of a CS dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized)



Disposal of Controlled Substance Waste



DEA allows disposal of Controlled Substance waste if:

- **It is authorized under your state's laws... and**
- **It is the remaining portion of used needles, syringes, or other injectable products in a practitioner environment**






[21 C.F.R. § 1304.21\(e\)](#)



Disposal of Controlled Substance Waste



 Record of waste disposal must include:

-  **Persons Handling Controlled Substance**
-  **Name of Substance/Form**
-  **Quantity**
-  **Date of Disposal**
-  **Manner of Disposal**

Records must be maintained at the practitioner's registered location for a **minimum of two years.**

Longer if required by state laws or regulations.



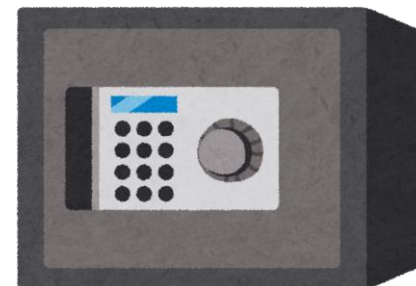
Security for Practitioners

All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. (21 CFR 1301.71)

Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet (21 CFR 1301.75b)

Best Practices:

- Safe
- Alarm System
- Camera System
- Limit Access to Controlled Substances



Registrant Inspections - Common Findings



- Lack of knowledge of software
 - Dispensing logs not maintained
 - Execution of DEA Form 222
 - Lack of required physical inventories such as initial and biennial inventories
 - No spill log (manual)
 - Spill log (electronic) not accurate
 - No checks and balances regarding spills
 - Not properly reconciling
 - Alarm systems not checked
 - Power of Attorney and lack of revocations
- Controlled substance accountability
 - Not counting everything on hand
 - Take back of controlled substances
 - Not notifying DEA of Drug Theft or Loss
 - Ordering controlled substances from other entities outside of the closed system of distribution
 - CSOS login and CSOS recordkeeping
 - Lack of complete and accurate records

Potential Administrative, Civil, and Criminal Actions



- Case closed or action taken
- Letter of Admonition
- Memorandum of Agreement
- Civil Fine
- Surrender of DEA Registration/Immediate Suspension of DEA registration
- Criminal Prosecution



Inspections - BEST PRACTICES



Designate a primary employee (and a back-up) to be responsible for controlled substance management

Conduct periodic internal inspections to stay fresh, identify weaknesses in the processes, and identify any compliance issues



Draft detailed policies and procedures for responding to DEA audits

Keep all controlled substance records in a single, easily-accessible location



Ensure that all controlled substances are maintained in secure areas





Case Studies



Dentist Sentenced to 15 Years in Prison for Stealing Drugs from Patients and Performing Surgery Without Proper Pain Management

December 2024

- Oral and maxillofacial surgeon
- Started stealing fentanyl from patients in December 2019
- Staff began noticing patients moving, moaning, and otherwise showing signs of pain and distress during surgery
- Admitted that he had stolen at least half of the fentanyl in every vial in the practice
- Acknowledged removing the safety caps, withdrawing at least half of the fentanyl in the single-use vials, refilling the vials with saline, and gluing the caps back on to the vials
- Made false entries into his surgical records claiming that he had given quantities of full-strength and unadulterated fentanyl to his patients to control their pain.
- Billed both public and private insurance for these surgeries utilizing these same falsified records
- Stole more than 40 grams of fentanyl for his personal use through his fraud
- At least 99 victims identified

Mother of patient testified about looking into the face of their child immediately following the surgery as the child cried and stated that they had “felt everything.”

Patient testified when she awoke during a procedure, Jensen struck the patient in the head with an instrument and completed the surgery, which involved the extraction of multiple teeth as well as the shaping and smoothing of the bones in her jaw, while she was conscious and lacking pain management.



Sentenced to 12 months-1 day in federal prison after pleading guilty

Pharmacist servicing LTCFs and hospice patients diverted hydromorphone

- Out of waste bins
- Claiming vials arrived broken in shipments
- Creating duplicate prescription entries in log books
- Undetected for at least nine months
- No known spread of infection/disease to patients but patients were often receiving end of life care

Signs:

- Volunteers to take the heavy waste bins from the clean room to storage closet
- Found bloody tissue and used alcohol pads in facility
- He was sleeping at his desk often
- Employee found bloody tissue, needle, and alcohol pad in employee bathroom

Employee Diversion

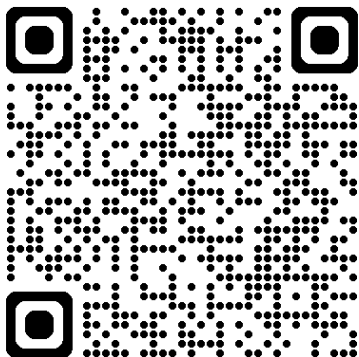


DRUG ADDICTION IN HEALTHCARE PROFESSIONALS



You should be cognizant of the fact that drug-impaired health professionals are one source of controlled substances diversion. Many have easy access to controlled substance medications; and some will divert and abuse these drugs for reasons such as relief from stress, self-medication, or to improve work performance and alertness.

WHAT IF I KNOW THAT DRUGS ARE BEING SOLD OR STOLEN?



- **Staff are ideal diverters - Addicted nurses and doctors (anesthesiologists have the highest rates of abuse) have easy access**
- **CDC estimate – 100,000 healthcare workers are addicts**
- **Can move from facility to facility – with no record of arrest, discipline, or investigation in many cases**
- **Patients (especially the elderly) may not know if someone stole their medication – but they can feel the results (e.g., waking up during surgery)**

Signs of Drug Diversion



- Suspicious behavior – lethargic, falling asleep at work
- Disappearing for long lengths of time
- Unusual access to the automated dispensing machine
- Disposal of medications with no witnesses
- Poor or no charting of patient medication
- Patients reporting higher pain levels during a specific employee's shift
- Employee always volunteers for overtime / open shifts in the OR
- Employee has excessive no – call / no shows or calls out frequently
- Employee has unexplained wealth or frequent new assets



Best Practices to Prevent Drug Diversion



Strong Medication Management



- Well-defined policies & procedures at pharmacy
- Secure storage, controlled access, complete records



Staff Education and Training



- Diversion awareness training
- Culture of accountability and vigilance
- Investigating and reporting practices

Audits and Inventory Controls



- Regular audits of controlled substance records
- Utilizing technology to monitor and detect diversion

Secure Medication Storage and Disposal



- Implementing physical security measures
- Proper disposal methods



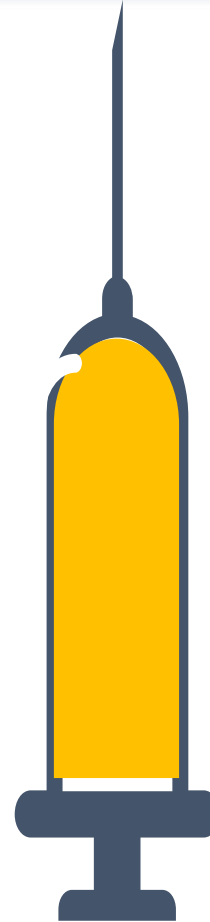
Diversion Effects All



Patients may receive inadequate pain relief, exposure to infectious diseases, substandard care



Facility/employer bears the cost of diverted drugs, internal investigations, civil fines and negative reputation



Health Care professionals risk overdose and possible death, face criminal prosecution, and malpractice suits



Community suffers though contributory drug misuse and mistrust in healthcare





**It is not personal
to closely
monitor
employees. It is
the cost of doing
business in a
highly regulated
industry.**





No single approach will mitigate all risks of diversion.

A multi-layered approach that addresses processes, practices, culture, security and strategy is recommended.





Assistance with Registration Matters

DEARegistration.Help@dea.gov | 1.800.882.9539

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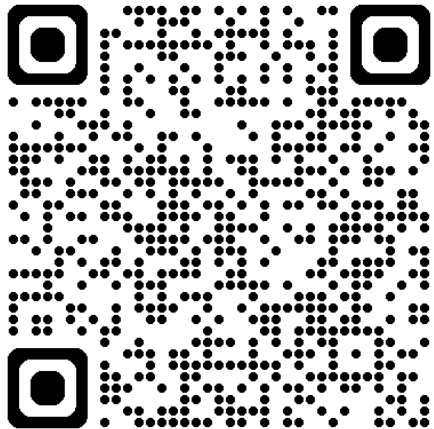
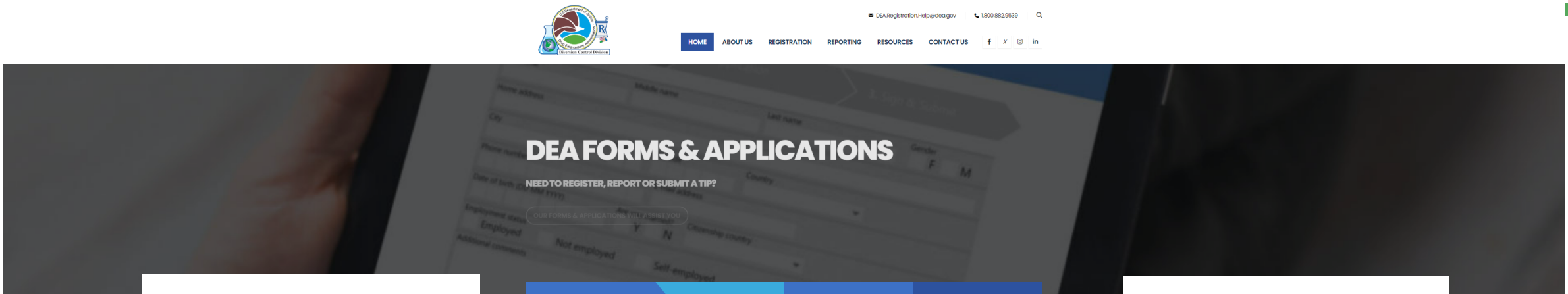
REGISTRATION FORMS & APPLICATIONS CONTACT US RESOURCES

You can find your local Registration Specialist

by visiting www.DEAdiversion.usdoj.gov

Contact us – Find Local Office

DEA Registration Resources



REGISTRATION FORMS & APPLICATIONS CONTACT US RESOURCES

We are resolving an issue with the NFLIS DQS functionality. We anticipate the problem will be resolved soon.

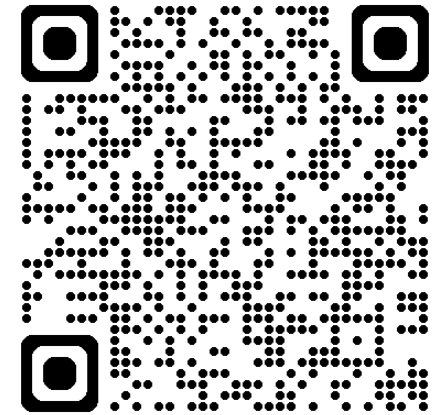
Multi-Factor Authentication added to the Registration Validation Toolset (PDF) (February 23, 2024)

Provide feedback for the website redesign here: deadiversionwebmaster@dea.gov

Welcome

Registration Forms & Applications Questions & Answers Meetings & Events

Go to Registration > Go to Forms > Go to Q&A > Go to Meetings >



[Diversion Control Division | Welcome \(usdoj.gov\)](https://www.usdoj.gov)

[eCFR :: Home](https://www.ecfr.gov)



Thank You!

RESOURCES FOR HEALTHCARE PROFESSIONALS



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About Us

HOME > ABOUT US

Program Description

Of all the major drugs of abuse, only marijuana is available as a natural, harvested product. The others, whether they are illicit drugs such as cocaine, heroin, methamphetamine, or legitimately produced pharmaceuticals, must be manufactured. Many problems associated with drug abuse are the result of legitimately made controlled substances being diverted from their lawful purpose into illicit drug traffic. The mission of DEA's Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

Diversion of Controlled Pharmaceuticals

Many of the narcotics, depressants, and stimulants manufactured for legitimate medical use are subject to abuse and have, therefore, been brought under legal control. Under federal law, all businesses that import, export, manufacture, or distribute controlled substances; all health professionals licensed to dispense, administer, or prescribe them; and all pharmacies authorized to fill prescriptions must register with the DEA. Registrants must comply with regulatory requirements relating to drug security and recordkeeping. The DEA is also obligated under international treaties to monitor the movement of licit controlled substances

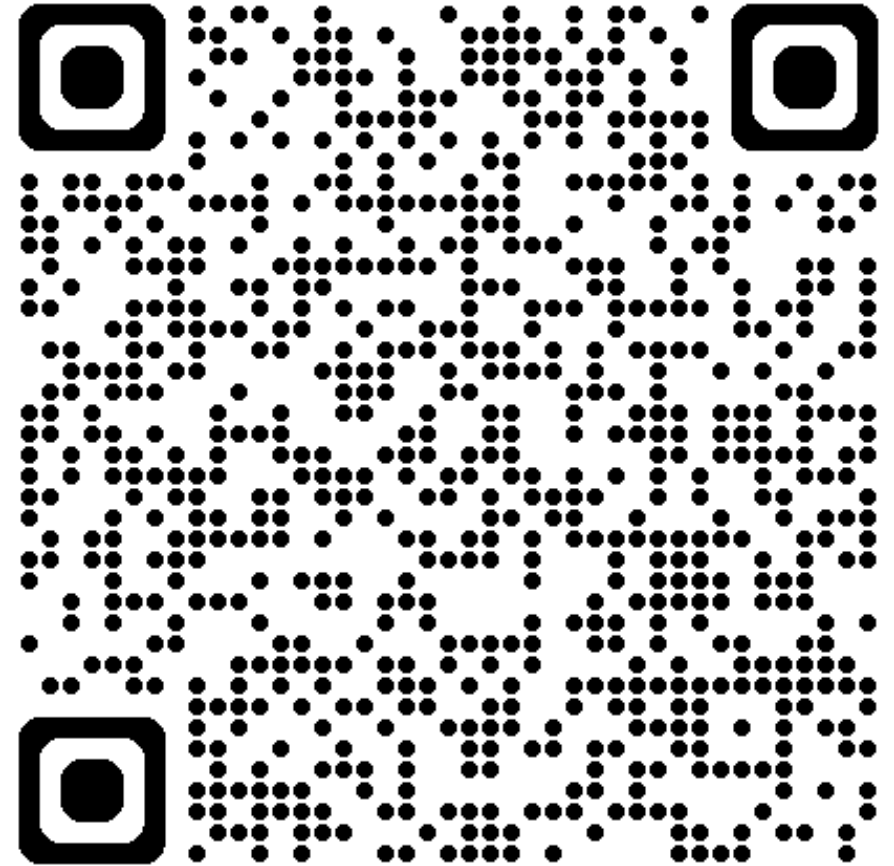


50

Years in Service

2

Million Registrants



Practitioner Manual

WWW.DEADIVERSION.USDOJ.GOV



Questions?

ODLL@DEA.gov



Webinar Evaluation

Complete the evaluation by **Friday, March 21** to receive CE credit. You will receive a link to the survey in 24 hours.

Next Webinar:

Oral Mucosal Lesions 101: Recognition, Risk Assessment, and Referral on **March 27 at 7 p.m. ET**

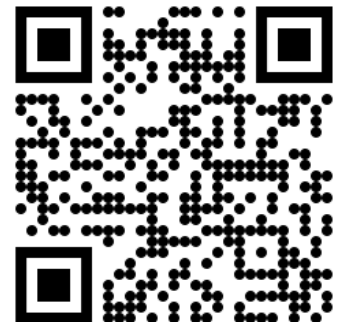
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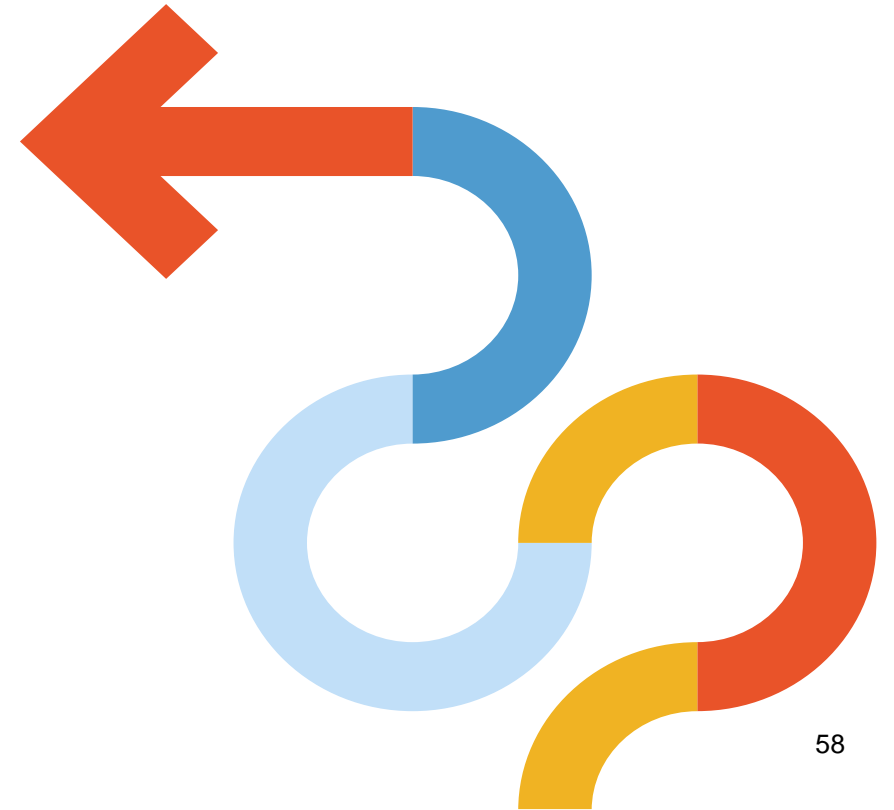
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