QUAD
GLOBAL ACCREDITATION AUTHORITY

DEA COMPLIANCE IN AMBULATORY SETTINGS: CONTROLLED SUBSTANCES, OPIOID UPDATES, AND RECORDKEEPING

Dennis Wichern

Retired DEA Agent

Prescription Drug Consulting

www.prescriptiondrugconsulting.com

Patients First. *Always.*

LEARNING OBJECTIVES

- Identify important controlled substance recordkeeping and security requirements at your ASC.
- Describe common drug diversion methods involving controlled substances and the risks they pose to your ASC.
- Recognize practical strategies and tips to reduce opioid risk at your ASC while complying with federal law.

CONFLICTS & DISCLOSURE STATEMENT

- I have no conflicts and no drug manufacturer affiliation.
- This is not a promotional talk for any pharmaceutical company.
- I will not discuss off-label/investigative use of any commercial product

WHO I AM

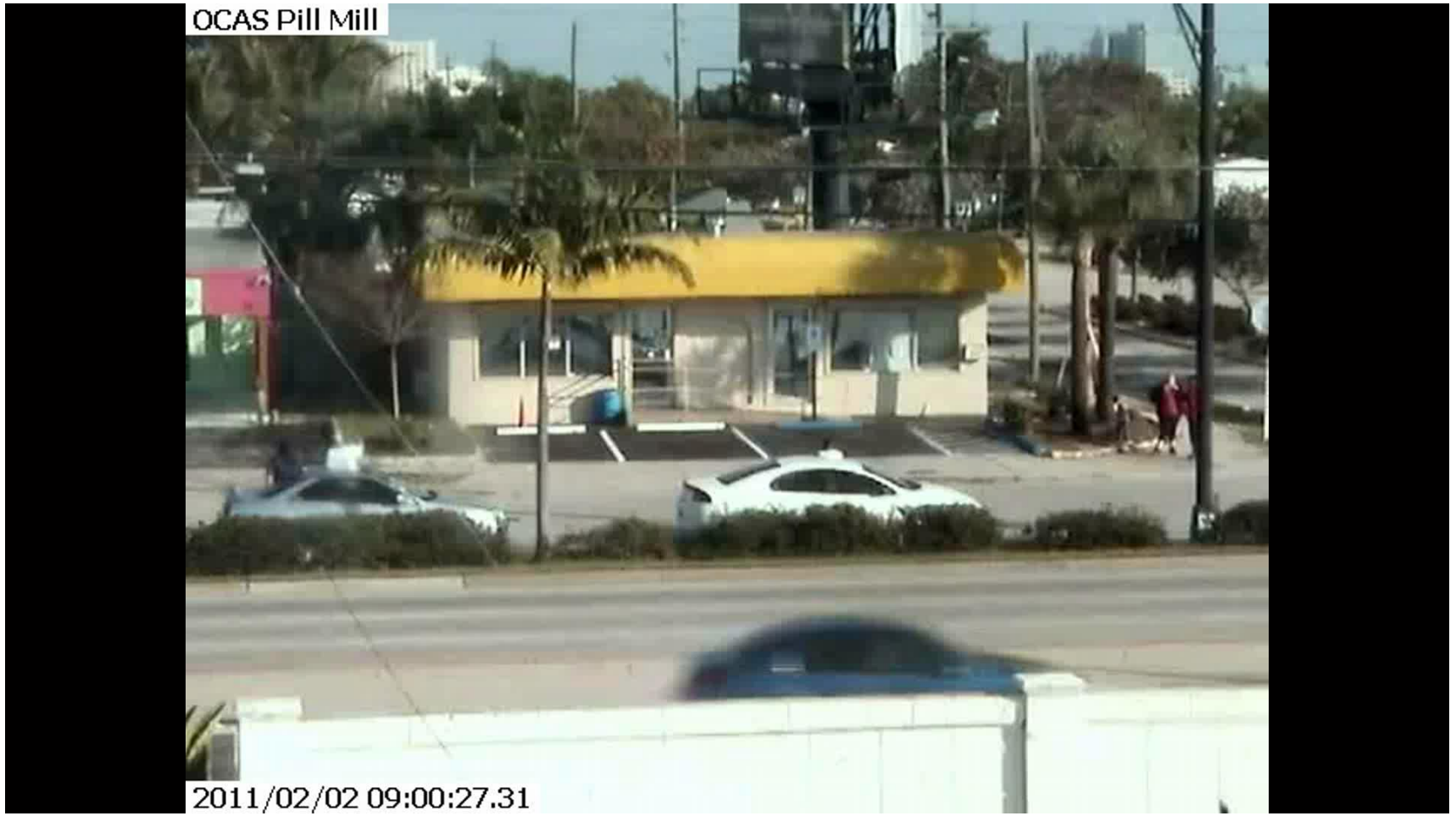
- Retired DEA Special Agent in Charge - Chicago.
- 30 years of experience.
- Have been partnering with medical community/prescribers for last 15 years through controlled substance training programs.
- Developer of DEA compliance, training and audit programs.
- I am not an attorney.
- I have no medical training.

PRESENTATION OUTLINE

- DEA Authority & Background
- DEA Registration
- DEA Recordkeeping and Security Requirements
- Drug Wasting & Drug Destruction
- Common Diversion Methods
- Diversion Prevention
- DEA Resources
- ASC Safeguards & Risk Mitigation
- Q & A

GIVE ME AN EXAMPLE OF A TYPICAL DEA OPIOID INVESTIGATION

FLORIDA PAIN CLINIC



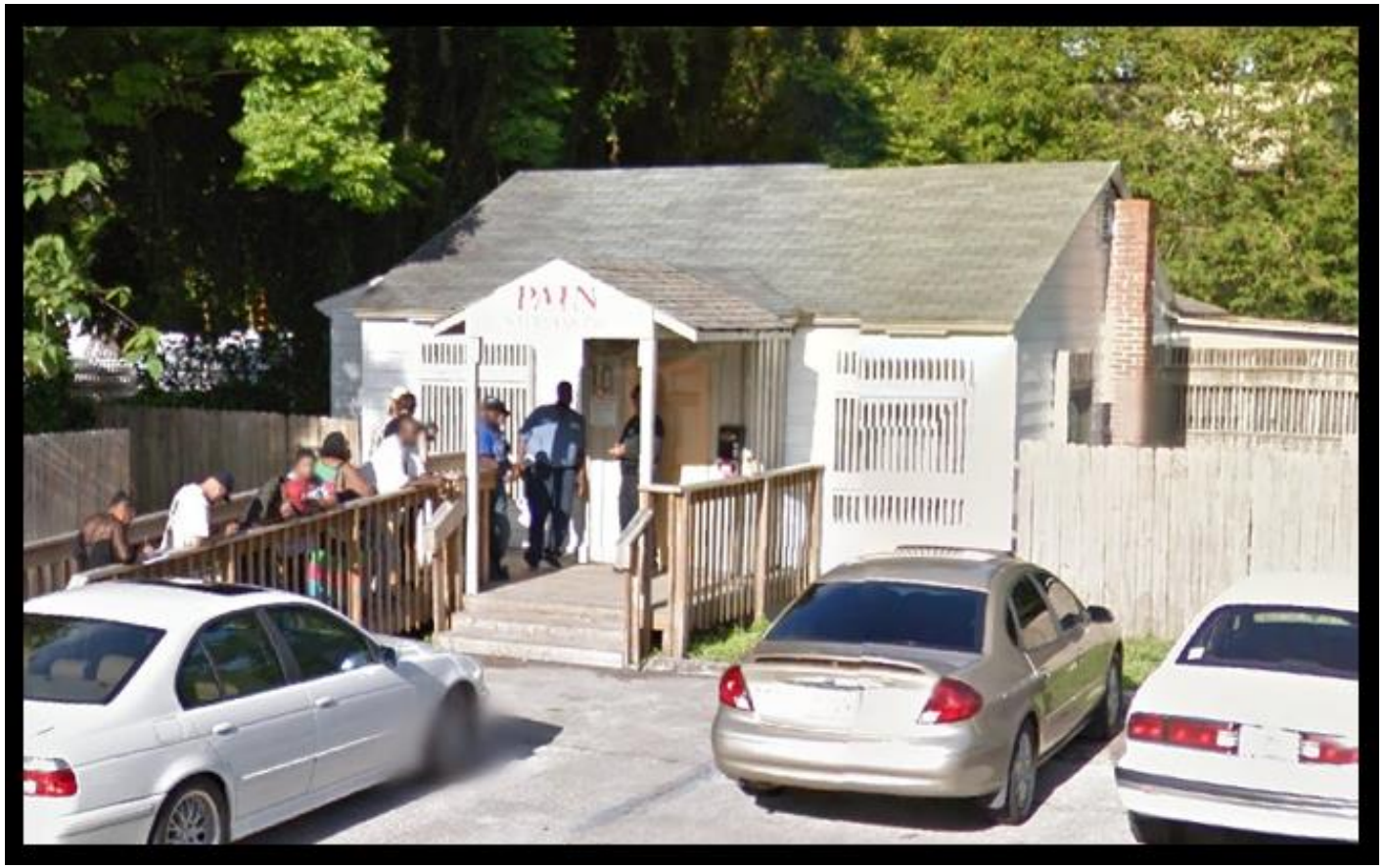
FLORIDA PAIN CLINIC

https://heroin.palmbeachpost.com/how-florida-spread-oxycodone-across-america/?ref=lowerTeases

FLORIDA PAIN CLINIC

Source: Miami Herald
http://media.miamiherald.com/static/media/projects/2014/innocents-lost/stories/pill-mills/

FLORIDA PAIN CLINIC



https://www.orangeobserver.com/article/pill-mill-pain-clinic-busted-winter-park

INDIANA PILL MILL

OHIO PILL MILL

https://medicine.wright.edu/sites/medicine.wright.edu/files/page/attachments/SciotoCounty.pdfslide 30

NEW YORK PAIN CLINIC

https://nymag.com/intelligencer/2014/02/rise-and-fall-of-nycs-biggest-pill-mill.html

INSIDE A PILL MILL

https://wsvn.com/news/inside-a-pill-mill

DEA AUTHORITY & BACKGROUND

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

DEA'S BACKGROUND

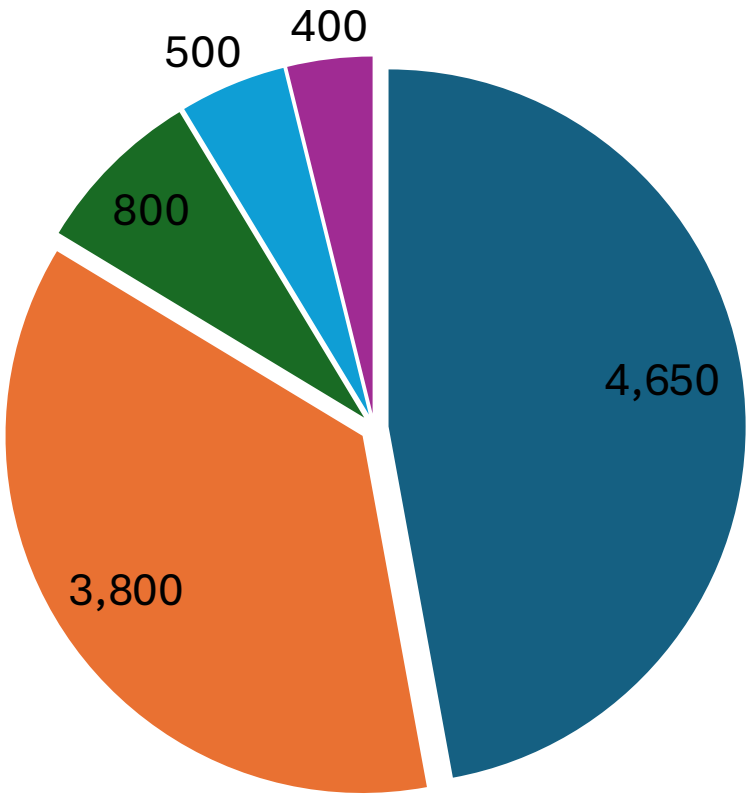
- Between 1914 and 1970, Congress enacted more than 50 pieces of legislation relating to the control and diversion of drugs. Most of these diverse laws were gathered into one piece of legislation, the CSA, which became effective May 11, 1971.
- In 1973, DEA was established to serve as the single federal agency to consolidate and coordinate the government's drug control activities.

https://www.cogan.com/documents/DEA_Controlled_Substances_Security_Manual.pdf page 7

DEA'S PRIMARY FOCUS & BACKGROUND

- Cartels, Gangs, and Criminal Organizations Trafficking Heroin, Fentanyl, Cocaine and Methamphetamine
- Not Ambulatory Settings
- However, DEA has oversight of pharmaceutical controlled substances (CS's)
- And is required by law to review those that use CS's daily

DEA PERSONNEL



- Approximately 9,848 Employees

Agents
PATC
Intel Analysts
Diversion Inv.
Chemists

*** PATC-Professional, Administrative, Technical, and Clerical**

DEA FIELD DIVISIONS – 23

- DEA has 241 Domestic Offices in 23 Divisions throughout the U.S. and 93 Foreign Offices in 69 countries

https://www.dea.gov/divisions

DEA'S ROLE WITH CONTROLLED SUBSTANCES

- DEA's statutory responsibility under the Controlled Substance Act (CSA) is twofold:
  - prevent diversion and abuse of drugs
  - ensure an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs.
- DEA has no providers on staff and must hire one to define standard of care if needed.

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

DEA'S ROLE WITH AMBULATORY CENTERS, PHARMACISTS & MEDICAL PROVIDERS

- DEA's authority under the CSA is not equivalent to that of a Board of Pharmacy or State Medical Board. DEA does not regulate the general practice of medicine.
- The responsibility for educating and training pharmacists & medical providers so that they make sound medical decisions in treating pain (or any other ailment) lies primarily with pharmacy and medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise.
- ***DEA's primary authority is limited to the recordkeeping and the security of pharmaceutical controlled substances.***

https://www.federalregister.gov/documents/2006/09/06/E6-14517/dispensing-controlled-substances-for-the-treatment-of-pain

NATIONWIDE DEA REGISTRANT POPULATION

	1/2018	1/2026
Practitioner	1,274,570	1,459,336
NP's & PA's	352,296	637,607
Pharmacy	72,716	65,107
Hospital Clinic	17,869	20,396
Manufacturer	575	516
Distributor	930	718
Researcher	11,440	9,518
NTP's	1,583	2,118
Analytic Labs	1,534	1,502

https://apps.deadiversion.usdoj.gov/RAPR/raprRegistrantPopulationSummary.xhtml#no-back-button

CONTROLLED SUBSTANCES ACT (CSA) OF 1970 21 USC

- Legal foundation of federal government's authority for controlled substances and listed chemicals.
- Under the CSA, Congress established a "closed system" of distribution to prevent the diversion of controlled substances.
- All persons who lawfully handle controlled substances must be registered with DEA or exempt from registration.
- Ultimate users (patients) are not required to register with DEA to possess controlled substances.

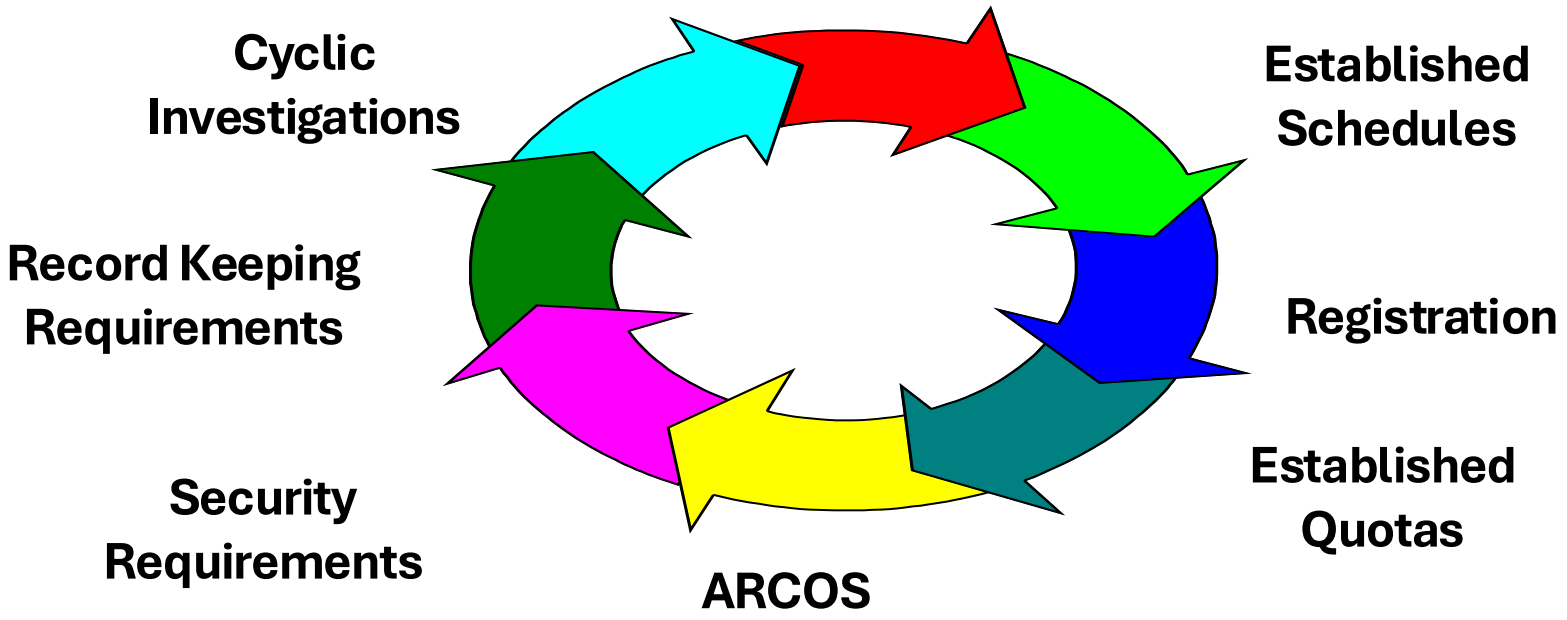
CODE OF FEDERAL REGULATIONS (CFR) PART 1300: SUBCOMPONENT OF CSA

- Legal foundation for DEA's oversight of pharmaceutical controlled substances.
- Contains recordkeeping and security requirements for pharmaceutical controlled substances.

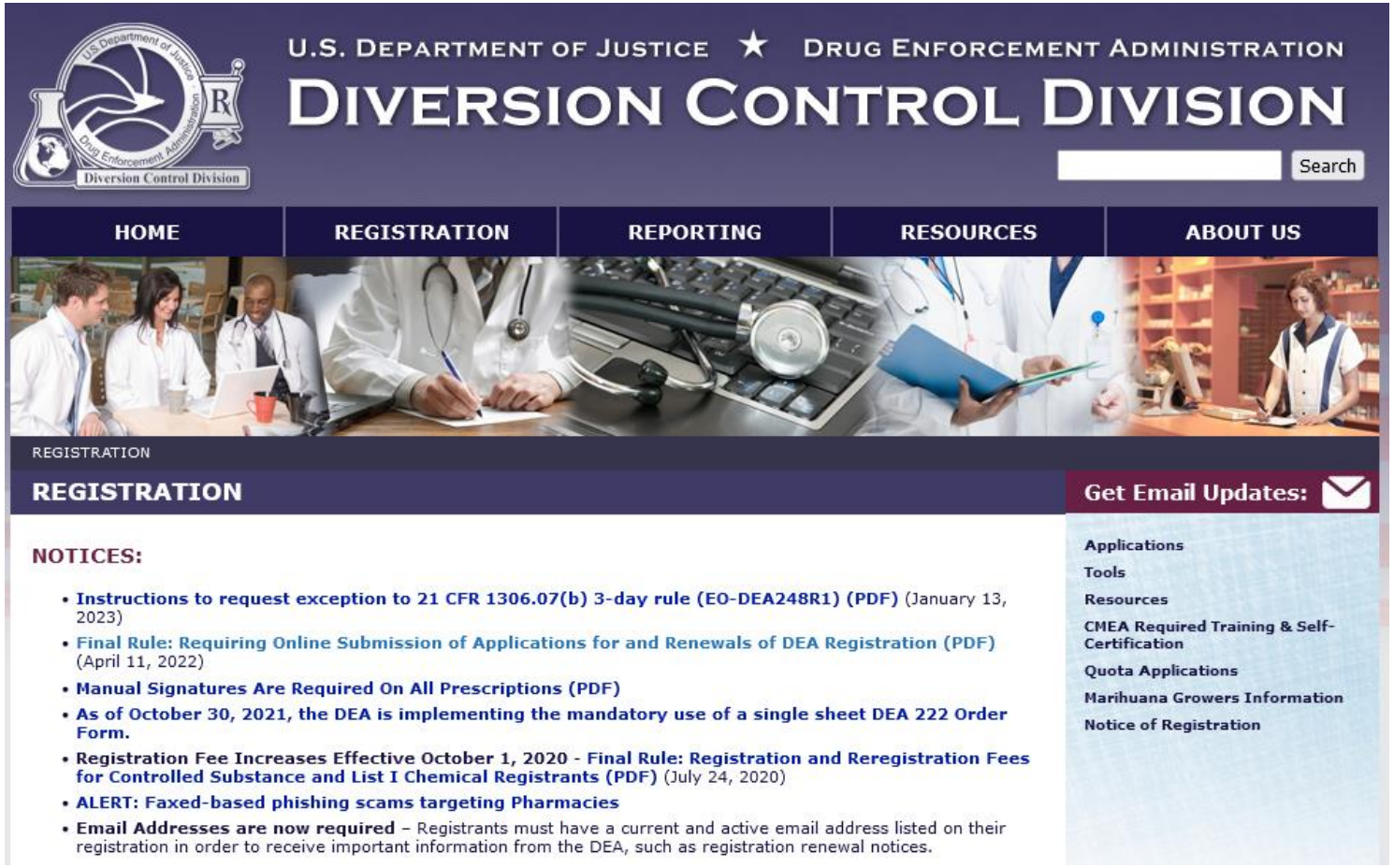
THE CSA'S CLOSED SYSTEM: EVERYONE IS REGISTERED

RECORDKEEPING FOR ALL CONTROLLEDSUBSTANCES

DEA DIVERSION CONTROL PROGRAM

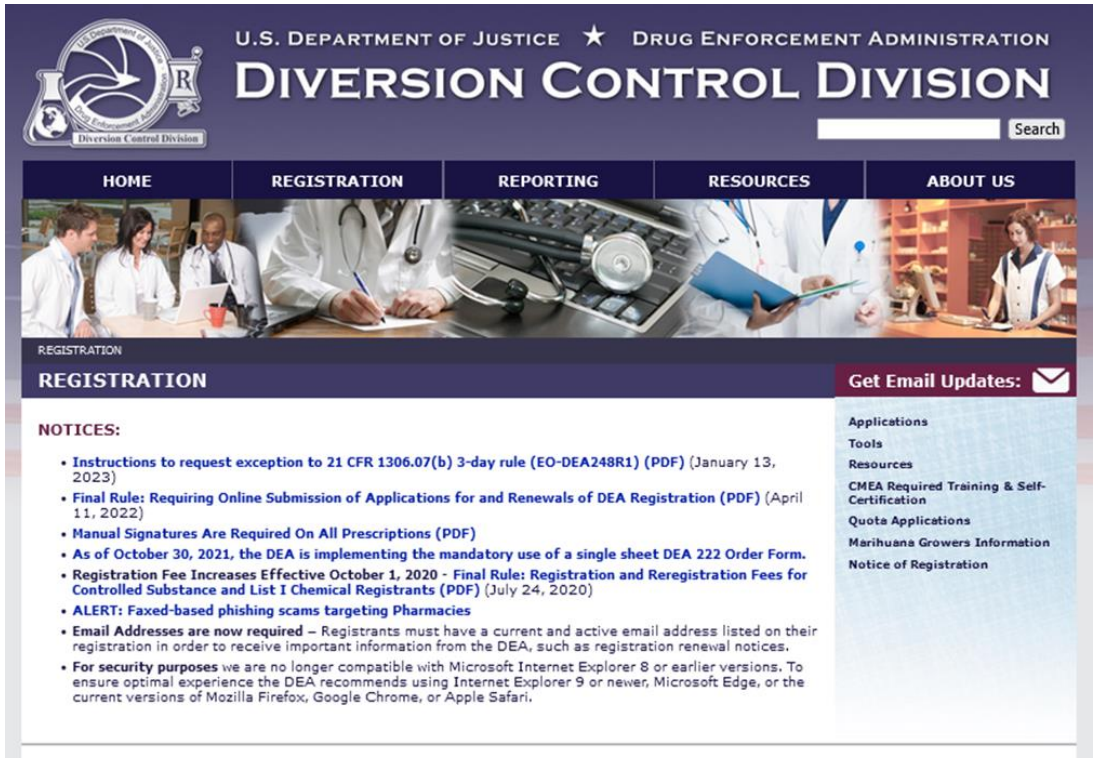


DEA REGISTRATION FOR AMBULATORY SETTINGS



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

DEA REGISTRATIONS



Key Reminders

- DEA will never issue a registration/license without a state approved registration first.
- DEA registrations and renewals must be submitted online as of 5/2022
- Help is at 1-800-882-9539 or DEA.Registration.Help@dea.gov
- All registrations actions can be performed at https://www.deadiversion.usdoj.gov/drugreg/index.html

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

DEA REGISTRATION WEBPAGE: TOP SECTION

- **Renewals Keys**
  - DEA will send out electronic renewal notices 60, 45, 30, 15, and 5 days prior to the expiration date of the registration.
  - Cannot renew prior than 60 days before expiration
  - One month grace period
  - If submitted prior to expiration, all good
  - ASC – three-year license
  - $888
  - Non-refundable
  - DEA form 224a (renewal)
  - DEA form 224 (new)

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

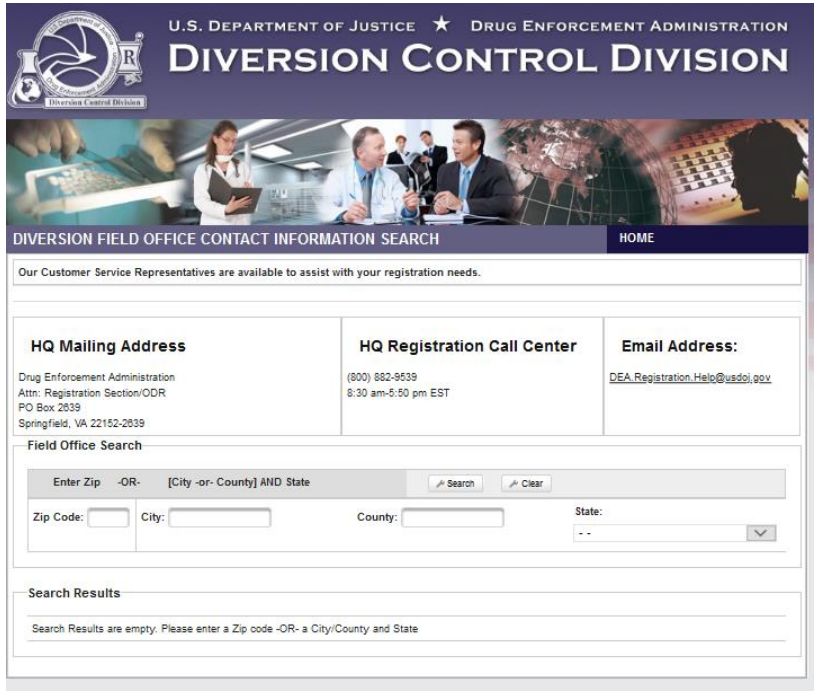
DEA REGISTRATION WEBPAGE: VERY BOTTOM SECTION- REGISTRATION ASSISTANCE

Registration Support

Call DEA Registration Service Center at **1-800-882-9539** (8:30 am-5:50 pm ET)

Email: DEA.Registration.Help@usdoj.gov - Be sure to include your DEA Registration number in your email.

Contact Local Registration Specialist



Keys

- Identify and communicate with local DEA registration specialist for better service if needed.
- Use HQS & 800 number as secondary POC's
- Human to human

https://www.deadiversion.usdoj.gov/drugreg/index.html
https://apps2.deadiversion.usdoj.gov/contactDea/spring/main?execution=e1s1

REGISTRATION & DRUG STORAGE

- A separate registration is required for every principal place of business, unless a registrant is only prescribing at a second location.
- If a registrant maintains supplies of controlled substances, administers, or directly dispenses controlled substances at that second location, a separate registration must be obtained.

https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_12.htm

ASC'S LOCATIONS NOT REGISTERED: CASE EXAMPLE

UNIVERSITY OF MICHIGAN
August 30, 2018

U.S. Attorneys » Eastern District of Michigan » News

Department of Justice

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U.S. Attorney's Office

Eastern District of Michigan

FOR IMMEDIATE RELEASE — Thursday, August 30, 2018

EASTERN DISTRICT OF MICHIGAN ANNOUNCES RECORD-SETTING HOSPITAL DRUG DIVERSION CIVIL PENALTY SETTLEMENT WITH THE UNIVERSITY OF MICHIGAN HEALTH SYSTEM

The United States Attorney's Office for the Eastern District of Michigan announced today that the University of Michigan Health System (UMHS) has agreed to pay the United States $4.3 million as part of a settlement resolving allegations that UMHS violated certain provisions of the Controlled Substances Act (CSA), 21 U.S.C. §§ 801-904. The settlement, which is civil in nature, resulted from a years-long Drug Enforcement Administration (DEA) investigation of UMHS's handling of controlled substances. It is the nation's largest settlement of its kind involving allegations of drug diversion at a hospital.

DEA began its investigation after two tragic incidents occurred in December 2013 involving two UMHS employees – a nurse and an anesthesiology resident. Both overdosed on opioids, including fentanyl, at a UMHS facility. The nurse's overdose was fatal.

SUMMARY

- Two overdoses in bathrooms
- 15 unregistered locations
- Overall lack of recordkeeping and controls
- Failure to report thefts and losses
- Three-year MOA

https://www.justice.gov/usao-edmi/pr/eastern-district-michigan-announces-record-setting-hospital-drug-diversion-civil

COMMON ISSUES IN AMBULATORY SETTINGS

Issue: CMO/surgeon leaves or retires and facility license in his/her name. His/her DEA # leaves with them.

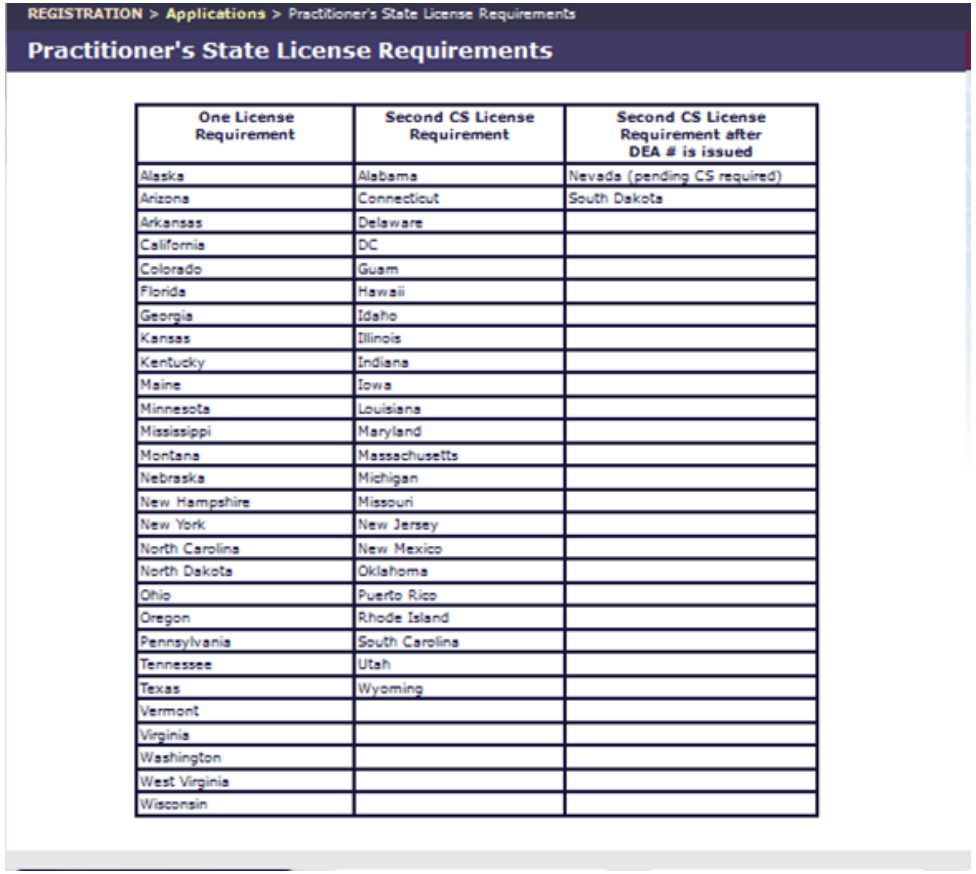
- Most facility registrations are either:
  - Hospital linked
  - Pharmacy linked
  - Facility/Standalone (LLC or similar)
  - Practitioner linked
- Business decision on how to register:
  - Consult with state first and then DEA
  - Facility/Standalone in long run might be best
  - DEA generally defers to state

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

COMMON REGISTRATION ISSUES

Issue: Provider moves from a one license state (medical license and CS license combined together) and applies to DEA but is unaware of second license need in new state .

All federal registrations/licenses contingent on state licenses



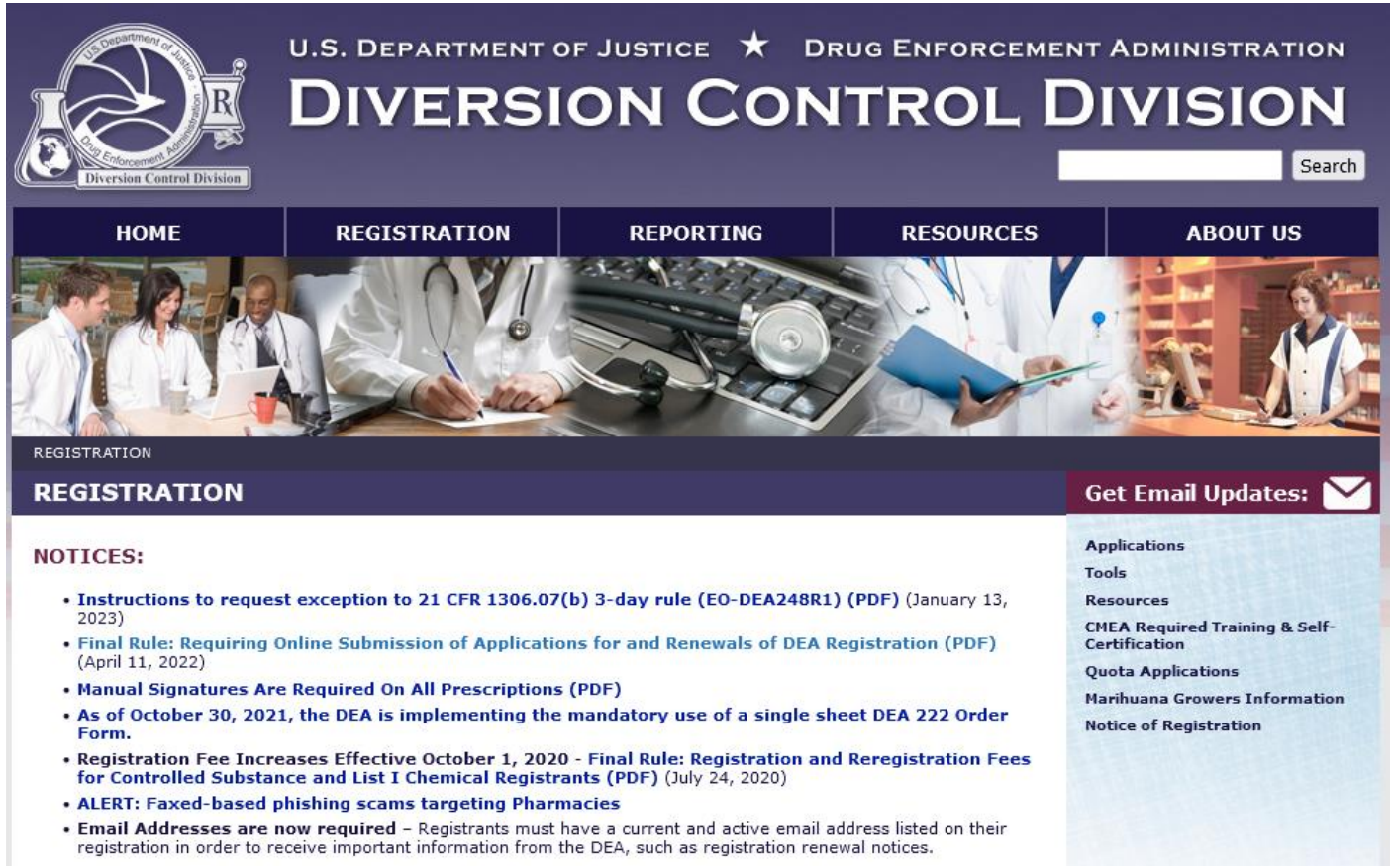
REGISTRATION > Applications > Practitioner's State License Requirements

Practitioner's State License Requirements

One License Requirement	Second CS License Requirement	Second CS License Requirement after DEA # is issued
Alaska	Alabama	Nevada (pending CS required)
Arizona	Connecticut	South Dakota
Arkansas	Delaware	
California	DC	
Colorado	Guam	
Florida	Hawaii	
Georgia	Idaho	
Kansas	Illinois	
Kentucky	Indiana	
Maine	Iowa	
Minnesota	Louisiana	
Mississippi	Maryland	
Montana	Massachusetts	
Nebraska	Michigan	
New Hampshire	Missouri	
New York	New Jersey	
North Carolina	New Mexico	
North Dakota	Oklahoma	
Ohio	Puerto Rico	
Oregon	Rhode Island	
Pennsylvania	South Carolina	
Tennessee	Utah	
Texas	Wyoming	
Vermont		
Virginia		
Washington		
West Virginia		
Wisconsin		

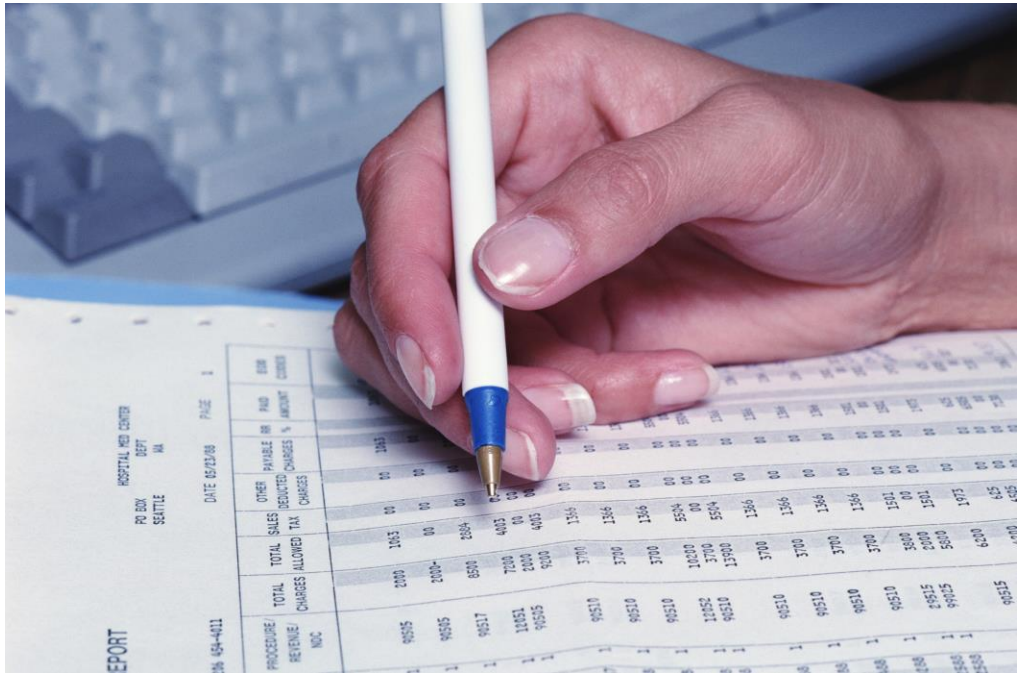
https://www.deadiversion.usdoj.gov/drugreg/index.html
https://www.deadiversion.usdoj.gov/drugreg/reg_apps/pract_state_lic_require.htm

DEA RECORDKEEPING & SECURITY REQUIREMENTS FOR AMBULATORY CENTERS



THE REQUIRED RECORDS

- POA's for II's
- Initial Inventory
- Biennial Inventory
- Closing Inventory
- Receiving Records, 222's or invoices – 2 - year federal retention/state?
- Distribution/Dispensing & Wasting Records
- Theft and Loss Records – 106's
- Drug Destruction & Returns -41
- Prescriptions vs Dispensing & Administering
- Must be "readily retrievable"
- Can be paper or electronic or both



https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist's_Manual_DEA.pdf pages 34 & 35

FACILITY SECURITY REQUIREMENTS

- DEA – “All registrants, including practitioners, shall provide effective controls and procedures to guard against theft and diversion of controlled substances. 21 CFR 1301.71(a). If a practitioner maintains a stock of controlled substances at their DEA registered office, the controlled substances must be stored in a securely locked, substantially constructed cabinet. 21 CFR 1301.75(b).”
- DEA views on security are somewhat subjective for non-manufacturers and distributors.
- Facilities should at minimum:
  - Keeps drugs in locked cabinet or room
  - Limit access to minimum of employees
  - Consider safe, alarm and cameras to bolster security which are today’s standard

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf page 41

General Requirements
CONTINUING RECORDS

Record requirements are different depending on whether the registrant is handling controlled substances in schedules I and II, or schedules III-V controlled substances. These requirements are also different depending on the type of registrant (business category) taking the inventory.

Kept for two years.
21 CFR. 1304.04(a)

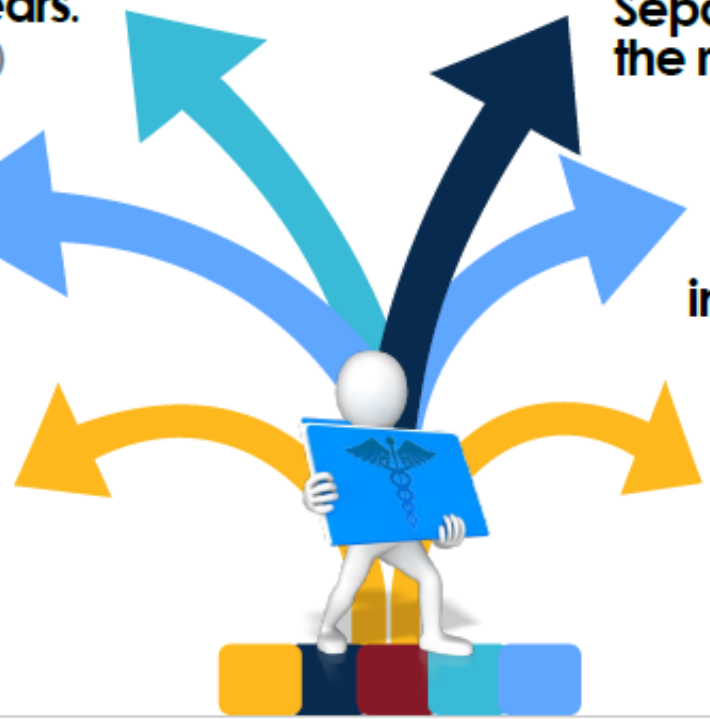
Separate and stored at the registered location.
21 CFR 1304.21(b)

Readily retrievable.
21 CFR 1304.04(f)(2)

Separate for each independent activity and collection activity.
21 CFR 1304.21(c)

Schedule I & II controlled substances must be maintained separately from all other records of the registrant.
21 CFR 1304.04(h)(1)

Complete and accurate.
21 CFR 1304.21(a)



If state requires longer record retention, you must follow more strict regulation.

DRUG WASTING

https://www.nytimes.com/2016/03/08/opinion/reducing-drug-waste-could-save-billions-of-dollars.html

WASTING & DEA

Waste Must be Made Non-Retrievable

Disposal of Controlled Substance Waste

DEA allows disposal of controlled substance waste if:

- It is authorized under your states laws… and
- It is the remaining portion of used needles, syringes, or other injectable products in a practitioner environment (hospital, clinic, physicians office, researcher, etc.)

U.S. Drug Enforcement Administration
Diversion Control Division

Witness profession is not defined

Records for disposal of waste

Recordkeeping for disposal of controlled substance waste:

- No DEA Form 41 required.
- Recommended that two employees witness the handling and the destruction of the controlled substance waste.

21 C.F.R. § 1317.95(c) and (d)
21 C.F.R. § 1304.21(e)

U.S. Drug Enforcement Administration
Diversion Control Division

https://www.deadiversion.usdoj.gov/mtgs/researcher_train/conf_2019/feb_2019/wingert.pdf slides #28 & 29

WASTING & DEA

Waste Must be Made Non-Retrievable

Disposal of Controlled Substance Waste

Record of waste disposal must include:

- Name of Substance
- Form
- Quantity
- Date of Disposal
- Manner of Disposal

21 CFR § 1304.22(c)

U.S. Drug Enforcement Administration
Diversion Control Division

Disposal

Requirements that apply to all controlled substance records required to be kept:

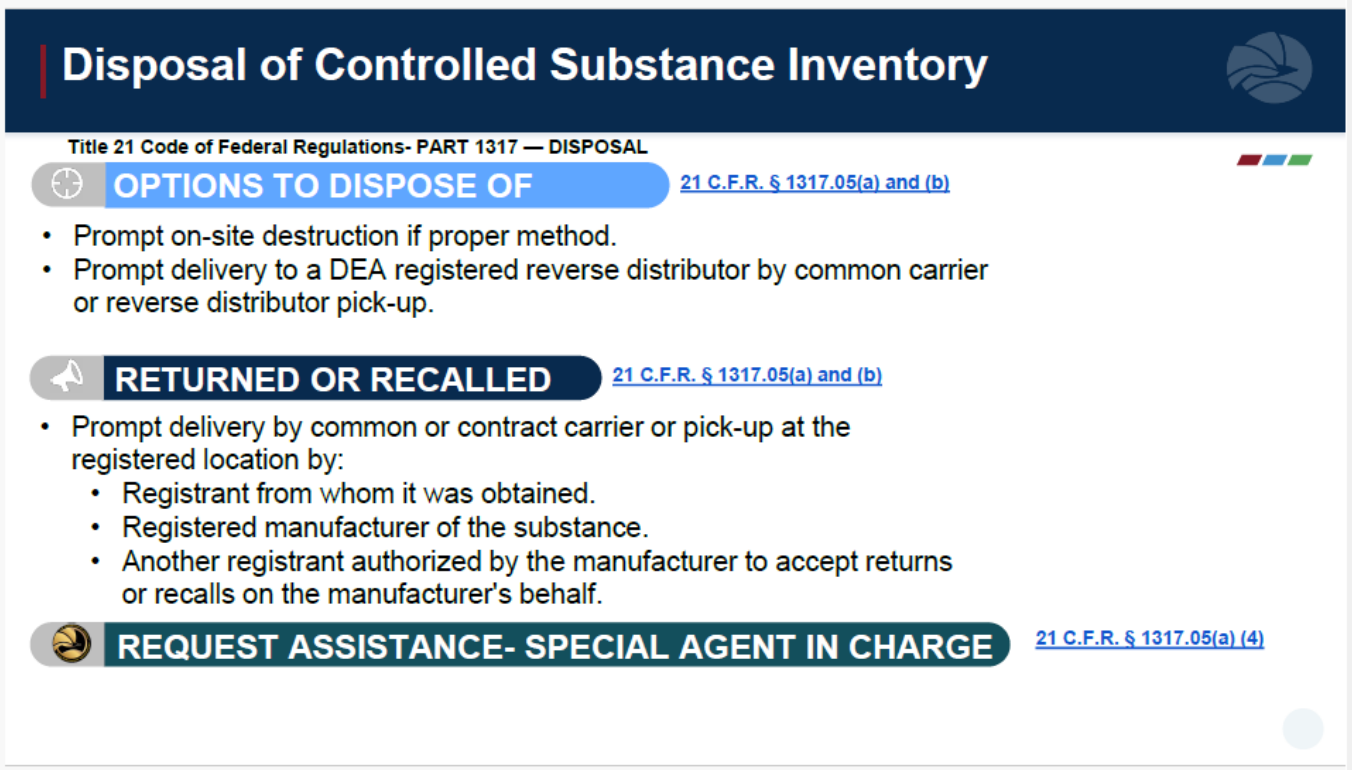
- Must be complete and accurate.
  21 C.F.R. § 1304.21(a)
- Must be stored at the registered location.
  21 C.F.R. § 1304.21(b)
- Must be kept for two years.
  21 C.F.R. § 1304.04(a)

U.S. Drug Enforcement Administration
Diversion Control Division

https://www.deadiversion.usdoj.gov/mtgs/researcher_train/conf_2019/feb_2019/wingert.pdf slides #30 & 35

DRUG DESTRUCTION

THREE WAYS TO DESTROY DRUGS



Law enforcement surrendering is only for ultimate users/patients/non-registrants

https://www.deadiversion.usdoj.gov/mtgs/supply_chain/conf_2025/Day_3/4_Preparing_for_a_DEA_Inspection.pdf

DRUG DESTRUCTION & WASTING RECEPTACLES ("NON-RETRIEVABLE")

MULTI-PURPOSE 2.5 GALLON CONTAINER CASE

DRUG DESTRUCTION & DEA FORM 41

Record for On-Site Disposal

- DEA Form 41 shall be used to record the destruction of all controlled substances using an on-site method that renders the controlled substances non-retrievable.
- DEA Form 41 shall include the names and signatures of the two employees who witnessed the destruction.

21 CFR § 1317.95(d)

OMB APPROVAL NO. 1117-0007 Expiration Date 04/30/2027

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.									

Spillage and broken vials should be recorded on a DEA 41.

https://www.deadiversion.usdoj.gov/mtgs/researcher_train/conf_2019/feb_2019/wingert.pdf page 26

INITIAL/QUARTERLY/ANNUAL/BIENNIAL INVENTORY REQUIREMENTS

1. The date of the inventory;
2. Whether the inventory was taken at the opening or close of business;
3. The name of each controlled substance inventoried;
4. The finished form of each of the substances (e.g., 10 milligram tablet);
5. The number of dosage units or volume of each finished form in each commercial container (e.g., 100 tablet bottle or 3 milliliter vial);
6. The number of commercial containers of each finished form (e.g., four 100-tablet bottles); and
7. A count of the substance. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the practitioner shall do as follows: If the substance is listed in schedule II, an exact count or measure of the contents is required. If the substance is listed in schedule III, IV, or V, an estimated count or measure of the contents is sufficient unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents is required.

Although it is not required by law, DEA recommends that registrants keep an inventory record that includes the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf page 38

INITIAL/QUARTERLY/ANNUAL/BIENNIAL INVENTORY EXAMPLE

Initial/Quarterly/Annual/Biennial Inventory

(Date Range)

_____ASC Name

Address _____

DEA #_____

Date _____

Opening or Close of Business (circle one/other)

CII or CII – V's (**must be on separate inventories**)

Signatures/two

_____

_____

Full Drug Name, Strength & Form	Full Vials/Bottles/Cartons	Partial Vials/Bottles	Actual Quantity	NDC Number (optional)
Fentanyl citrate solution, 50 mcg/mL, 1 mL vial, (25 count package)	4	17	117	NDC 63323-0806-01
Hydrocodone bitartrate and Acetaminophen tablet, 5 mg / 325 mg, (100 count bottle)	3	22	322	NDC 10702-0189-01

DISPENSING LOG REQUIREMENTS

- “If authorized by state law, a practitioner may dispense controlled substances to patients. Practitioners must maintain records of the quantity dispensed, the name and address of the person to whom it was dispensed, the date dispensed, and the written or typewritten name or initials of the individual who dispensed the controlled substance on behalf of the practitioner. 21 CFR 1304.22(c).”
- Also need drug name, form and strength.
- Can always exceed minimum data requirements

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf page 37

DISPENSING LOG EXAMPLE

Sample Dispensing[4] & Wasting Log[5]

21 CFR 1304.22(c), 21 CFR 1304.21(e) & 21 CFR 1317.95(d)

Organization and address: _____
DEA# _____

1) Drug Name: _____, **Form:** _____, **Strength:** _____
NDC# _____
2) Drug Name: _____, **Form:** _____, **Strength:** _____
NDC# _____

Date	Patient Name & Address	_____ Amount Dispensed	_____ Amount Dispensed	Initials of Person Dispensing	Wasting Amount?	Wasting Witness #1 Name and signature	Wasting Witness #2 Name and signature

PERPETUAL INVENTORY AND DAILY COUNTS

- Neither are required by DEA
- CFR specifically mentions that perpetual inventory is not required
- One can always exceed DEA basic requirements
- Smart to institute both
- Perfect records equal perfect outcomes

- “All registrants shall provide effective controls to prevent diversion.” (Training, policies, enhanced security, & more)

DRUG TRANSFERS AMONGST REGISTRANTS

- Perfectly allowable
- Must execute a 222 or invoice every time
- Most agencies forget to execute 222 or invoices
- Don’t - unless truly needed
- Use straight line accounting to reduce risk
- 5% rule
- Perfect records equals perfect outcome

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf pages 31 & 37

SIGNIFICANT LOSS DEFINED

Although the CSA and the regulations do not define the term “significant loss,” it is the responsibility of the registrant to use his or her best judgment to take appropriate action. Whether a “significant loss” has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer. Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. Pursuant to 21 CFR 1301.76(b), the burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

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; and
6) Local trends and other indicators of the diversion potential of the missing controlled substances.

If it is determined that the loss is not significant, DEA recommends that the registrant place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management’s discretion.

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist%27s_Manual_DEA.pdf pages 62 & 63

DEA 106 REPORTING

- Under 21 CFR 1301.76(b), should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented **within one business day of the discovery** of the theft or loss.

- Only DEA form sent to DEA

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist%27s_Manual_DEA.pdf pages 61 & 62

DEA "BLACK BAG" EXCEPTION

DEA Registration Limits

Unique exception: The Medical Bag. Administering or dispensing a controlled substance inside a state where a practitioner is registered, but at other than the practitioner's DEA registered location.

Note: Random and as needed is – fact specific

U.S. Drug Enforcement Administration
Diversion Control Division

https://www.deadiversion.usdoj.gov/mtgs/pract_awareness/conf_2020/feb_2020/index.html slide #24
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-047)(EO-DEA212)_QA_re_Black_Bag_Exception_(Final).pdf

DEA "BLACK BAG" EXCEPTION

(Might Need Another Registration Number?)

Title: Practice of Medicine

Question: Can a physician transport controlled substances and administer at the patient's home residence (the so-called "black bag exception")?

Answer: Yes, with a limit. DEA will permit a physician who is registered with DEA to dispense controlled substances at a particular location in a state to travel to other unregistered locations in the *same state* to dispense controlled substances on an "as-needed and random basis," so long as the physician does not maintain a principal place of professional practice at any of those unregistered locations. *See Jeffery J. Becker, D.D.S.*, 77 FR 72387, 72388 (Dec. 05, 2012); *see also* 21 U.S.C. 822(e)(1), 21 CFR 1301.12(b)(3). If a physician intends to dispense controlled substances from a particular location several times a week or month, he must first file a separate registration for the location. *See Moore Clinical Trials, L.L.C.*, 79 FR 40145-02,

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-047)(EO-DEA212)_QA_re_Black_Bag_Exception_(Final).pdf

DEA “BLACK BAG” EXCEPTION

Registrants Required Records:

- POA’s for II’s
- Initial Inventory
- Biennial Inventory
- Closing Inventory
- Receiving Records, 222’s or invoices – 2 - year federal retention/state?
- Distribution/Dispensing & Wasting Records
- Theft and Loss Records – 106’s
- Drug Destruction & Returns -41
- Prescriptions vs Dispensing & Administering
- Must be “readily retrievable”
- Can be paper or electronic or both
- Stored at registrants listed location

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist's_Manual_DEA.pdf pages 34 & 35

WHAT DRUGS SHOULD I FOCUS ON?

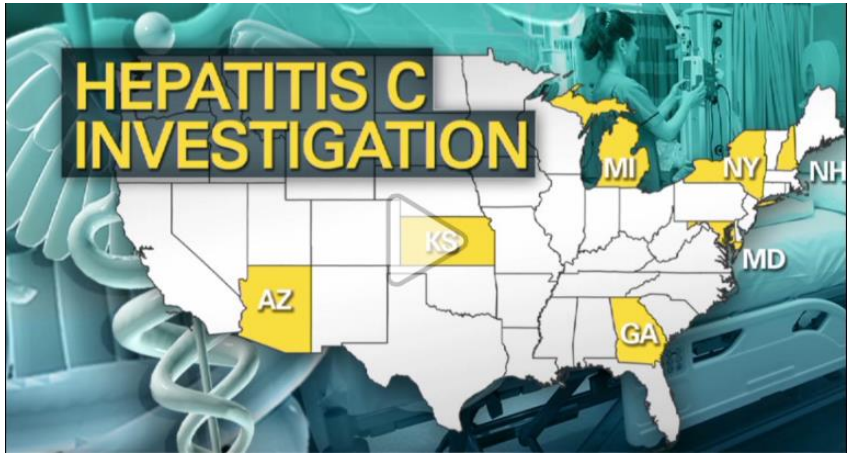
THE KEY ASC DRUGS

- It will always be about the opioid syringes
- Fentanyl, morphine, etc.
- And the benzodiazepines – Versed, etc.

SURGERY CENTER RELATED CASE STUDIES

MULTI-STATE HEPATITIS OUTBREAK 2011

- David Kwiatkowski
- A cardiac technologist in 18 hospitals in seven states before being hired at New Hampshire's Exeter Hospital in 2011.
- Had moved from job to job despite being fired at least four times over allegations of drug use and theft.
- Since his arrest last year, 46 people have been diagnosed with the same strain of hepatitis C he carries.
- Kwiatkowski admitted stealing the injectable painkiller fentanyl and replacing them with saline-filled syringes tainted with his blood.
- Sentenced to 39 years in prison
- How a nurse defeated him



https://www.newsweek.com/2015/06/26/traveler-one-junkies-harrowing-journey-across-america-344125.html

JUSTICE DEPARTMENT ANNOUNCES SETTLEMENT AGREEMENT WITH SEATTLE CANCER CARE ALLIANCE OVER PHARMACY CONTROL FAILURES

July 7, 2016

WASHINGTON - The Department of Justice announced today that it has reached a settlement with Seattle Cancer Care Alliance (SCCA) relating to losses of more than 96,000 pills of oxycodone between 2011 and 2013. SCCA self-reported the diversions after discovering that a nurse employed at the cancer care center had used falsified and altered prescriptions to divert oxycodone from SCCA's on-site pharmacy.

The nurse conducted the scheme by drafting prescriptions for patients who were formerly receiving care at the center, obtaining physician signatures on those prescriptions, and then altering the prescriptions to reflect higher quantities and doses before transmitting them to the on-site pharmacy to be filled.

The nurse would then pick up the controlled substances from the pharmacy under the guise that she was doing so as a service to the patient.

https://www.justice.gov/usao-wdwa/pr/justice-department-announces-settlement-agreement-seattle-cancer-care-alliance-over

RED RIVER COUNTY NURSE GUILTY OF STEALING FENTANYL FROM HOSPITAL EMPLOYER

July 28, 2023

SHERMAN, Texas – An Annona, Texas nurse has pleaded guilty to federal violations in the Eastern District of Texas, announced U.S. Attorney Damien M. Diggs today. Crystal McLin Lipe, 41, pleaded guilty on July 27, 2023, to obtaining a controlled substance by fraud before U.S. Magistrate Judge Aileen Goldman Durrett.

According to court documents presented in court, Lipe worked as a registered nurse in the Intensive Care Unit (ICU) of a hospital in the Eastern District of Texas. At various points during her time with the hospital, Lipe knowingly accessed and obtained fentanyl, a controlled substance under federal law, for personal use without the hospital's authorization. In particular, Lipe acquired the fentanyl fraudulently, by removing the fentanyl from its original vials, replacing the fentanyl with a liquid containing sodium chloride, and failing to disclose her conduct to the hospital.

https://www.justice.gov/usao-edtx/pr/red-river-county-nurse-guilty-stealing-fentanyl-hospital-employer

IOWA NURSE SENTENCED TO FEDERAL PRISON AFTER STEALING PAIN MEDICATION FROM AT LEAST 50 NEW MOTHERS AT WATERLOO HOSPITAL

April 1, 2024

- An Iowa nurse who stole pain medication from at least 50 new mothers at a Waterloo hospital was sentenced on March 27, 2024, in federal court in Cedar Rapids, Iowa. Christina Eileen Olson, formerly known as Christina Eileen Hovey, age 43, of Waterloo, received the prison term after pleading guilty on October 12, 2023, to one count of acquiring a controlled substance by misrepresentation, fraud, deception, and subterfuge, one count of adulteration and misbranding with intent to defraud and mislead, and one count of false statements relating to health care matters.

- At the plea hearing, and in a plea agreement, Olson admitted that the State of Iowa granted her a nursing license in 2004. In 2017, a Waterloo hospital hired Olson to work as a nurse in its labor and delivery unit. Olson was responsible for caring for late-term pregnant women, women in active labor, and post-partum women, including women recovering from recent Caesarean section ("c-section") surgery. Obstetricians prescribed these women Schedule II narcotics, including hydromorphone, oxycodone, and fentanyl, in order to control physical pain associated with the birthing process.

https://www.justice.gov/usao-ndia/pr/iowa-nurse-sentenced-federal-prison-after-stealing-pain-medication-least-50-new

FORMER NURSE SENTENCED TO FEDERAL PRISON FOR TAMPERING WITH A CONSUMER PRODUCT

July 6, 2023

MIAMI – Catherine Shannon Dunton, 55, has been sentenced to 48 months in prison, followed by three years of supervised release, for stealing fentanyl from sterile vials intended for patients for personal use and then replacing the fentanyl with saline solution to avoid detection.

From February 28 to April 18, 2022, Dunton, a Florida licensed Registered Nurse (RN), worked at an outpatient surgical center in Jensen Beach, Martin County, Fla. as a circulating nurse. While working at the center, Dunton took vials of fentanyl, a narcotic painkiller in liquid form, and self-administered it by injection. To avoid detection, she replaced the fentanyl from nearly 450 vials with saline solution, and then returned the adulterated vials to the center for use during outpatient surgical procedures.

https://www.justice.gov/usao-sdfl/pr/former-nurse-sentenced-federal-prison-tampering-consumer-product

FORMER NURSE PLEADS GUILTY TO DRUG DIVERSION FROM BOSTON-AREA HOSPITAL

August 4, 2023

BOSTON – A former nurse pleaded guilty in federal court today in Boston to diverting opioids from a Boston-area hospital. Andrea Falzano, 39, of Winchester, pleaded guilty to three counts of unlawfully obtaining controlled substances by fraud, deception, and subterfuge. U.S. District Court Judge Nathaniel M. Gorton scheduled sentencing for Nov. 14, 2023. Falzano was indicted on Feb. 24, 2023.

According to admissions made in connection with her guilty plea, beginning in May 2019, Falzano used her capacity as a nurse in the emergency department at a Massachusetts based hospital to withdraw controlled substances from a locked drug cabinet. These substances included morphine, fentanyl, and hydromorphone, all of which are opioids and Schedule II controlled substances. In total, Falzano withdrew these substances 412 times for 299 already discharged patients over an approximately five-month period.

https://www.justice.gov/usao-ma/pr/former-nurse-pleads-guilty-drug-diversion-boston-area-hospital

NURSE CHARGED WITH TAMPERING WITH LORAZEPAM VIALS

October 6, 2023

Vanessa Roberts Avery, United States Attorney for the District of Connecticut, today announced that a federal grand jury in New Haven has returned an indictment charging SEAN FALZARANO, 37, of Southbury, with five counts of tampering with a consumer product.

The indictment alleges that, on January 31, 2022, Falzarano an RN took five vials containing 2mg/ml of Lorazepam solution that he knew was intended to be dispensed to patients, removed the Lorazepam solution from the vials, replaced it with saline, and returned the adulterated vials to be used in medical procedures.

https://www.justice.gov/usao-ct/pr/nurse-charged-tampering-lorazepam-vials

IOWA NURSE PLEADS GUILTY TO DIVERTING FENTANYL AT WATERLOO HOSPITAL

October 11, 2023

An Iowa nurse who diverted fentanyl at a Waterloo hospital pled guilty today in federal court in Cedar Rapids. Luis Ramirez-Cajas, age 42, from Cedar Rapids, was convicted of one count of acquiring a controlled substance by misrepresentation, fraud, deception, and subterfuge.

In September and October 2022, while working at the Waterloo hospital, Ramirez-Cajas diverted fentanyl, hydromorphone, and morphine to his own use. Ramirez-Cajas diverted the drugs mostly through purported wasting—falsely documenting in the Waterloo hospital's records, for example, that he had wasted a full vial because a patient purportedly had refused the drug after Ramirez-Cajas pulled it. Instead of wasting the controlled substances, Ramirez-Cajas diverted them for personal use.

https://www.justice.gov/usao-ndia/pr/iowa-nurse-pleads-guilty-diverting-fentanyl-waterloo-hospital

ORTHOPEDIC SURGEON CONVICTED OF HEALTH CARE FRAUD

December 14, 2023 – Defendant was one of the top prescribers of opioids in Massachusetts.

- BOSTON – A Canton orthopedic surgeon has been convicted by a federal jury in Boston for his role in a health care fraud scheme. Dr. Olarewaju James Oladipo, 60, of Canton, was convicted on Dec. 12, 2023 of 10 counts of health care fraud.
- From approximately January 2016 through December 2019, Oladipo devised and executed a scheme to defraud health care benefit programs by falsely billing for patient visits. Specifically, Oladipo used billing codes for more complex—and thus more expensive—services that were not provided (a practice that is sometimes referred to as "upcoding"). Oladipo falsified medical records of patient visits to reflect examinations and services that were not performed.
- During the four-year period, Oladipo frequently billed for more than 60 patients per day and sometimes more than 90 patients per day. The result was that many, if not most, of Oladipo's patient visits on such days could have only lasted five minutes or less. However, Oladipo used billing codes that typically corresponded to visits of 15, 25, 30, or even 45 minutes. Additionally, Oladipo ensured this high flow of patients to his practice by prescribing powerful, highly addictive opioids at a rate that made him one of the top prescribers of such drugs in Massachusetts.

https://www.justice.gov/usao-ma/pr/orthopedic-surgeon-convicted-health-care-fraud

DENTIST SENTENCED TO 15 YEARS IN PRISON FOR STEALING DRUGS FROM PATIENTS AND PERFORMING SURGERY WITHOUT PROPER PAIN MANAGEMENT

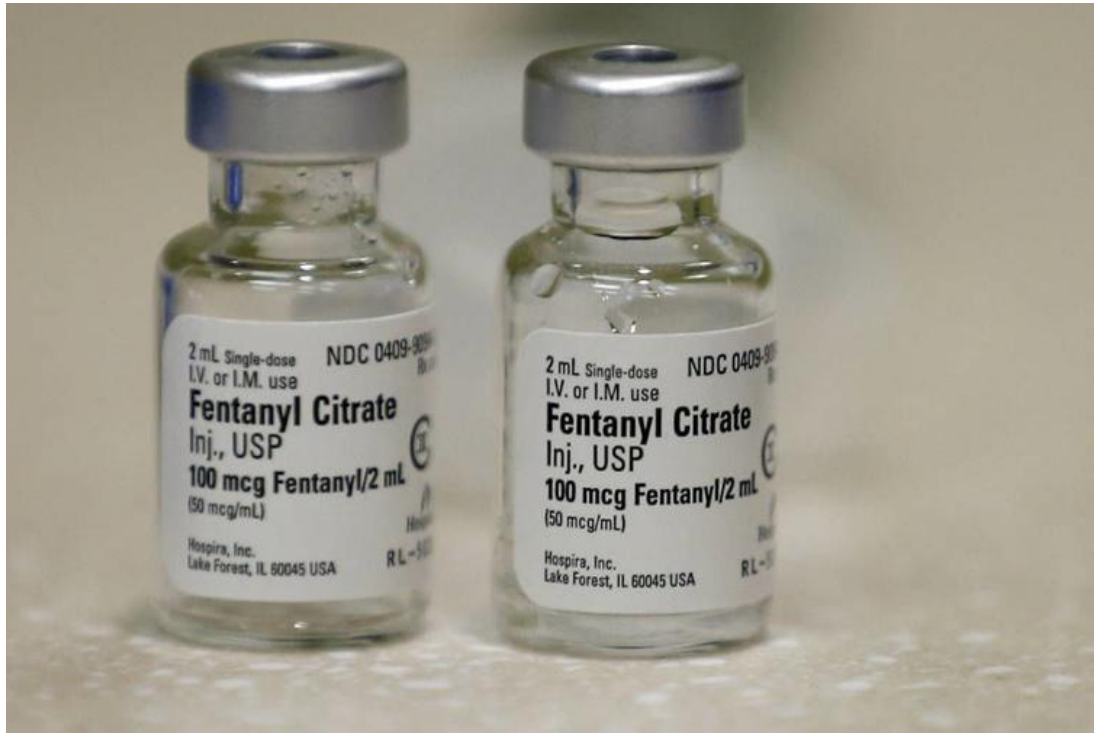
December 20, 2024

- SPRINGFIELD, Ill. – A Rochester, Illinois, dentist, Phillip M. Jensen, 64, was sentenced on December 18, 2024, to 15 years in prison for stealing fentanyl from his patients, injecting them with adulterated drugs, and performing surgery without proper pain management. Jenson also was ordered to pay a $200,000 fine. Jensen previously pleaded guilty to two counts of drug diversion, two counts of acquiring a controlled substance by fraud, one count of tampering with consumer products resulting in serious bodily injury, and two counts of false statements relating to health care matters in August 2024.
- Jensen, who prior to having his license suspended in 2022 had specialized in oral and maxillofacial surgery, started stealing fentanyl form his patients as early as December 2019. This conduct first came to light when his staff began noticing patients who were moving, moaning, and otherwise showing signs of pain and distress during surgery.
- Jensen admitted that he had stolen at least half of the fentanyl in every vial in the practice. He 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. In a further effort to hide what he had done, Jensen 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. He further billed both public and private insurance for these surgeries utilizing these same falsified records. In all, Jensen stole more than 40 grams of fentanyl for his personal use through his fraud.

https://www.justice.gov/usao-cdil/pr/dentist-sentenced-15-years-prison-stealing-drugs-patients-and-performing-surgery

DIVERSION PREVENTION IN AMBULATORY SETTINGS

- Limit drug access to minimum necessary
- Keep drugs secure at all times
- Use rule of two when accessing drugs
- Audit drugs frequently
- Check vial caps and quantities for irregularities
- Waste only with a witness
- Secure drug waste and make it non-retrievable



ADDITIONAL DIVERSION PREVENTION INFORMATION

HEPATITIS OUTBREAK: FLORIDA, MAYO CLINIC

- Radiology technician
- Employed at Mayo Clinic from 2004 to 2010
- Switched patients' fentanyl syringes with saline solution infected with hepatitis C
- Mayo Clinic implemented significant changes as a result of this case

By CRIMESIDER STAFF / CBS NEWS / *September 12, 2012, 11:58 AM*

Steven Beumel, former radiology technician, sentenced to 30 years in prison for infecting patients with Hepatitis C

A former radiology technician at the Mayo Clinic who caused a hepatitis C outbreak by swapping patients' syringes and led to one person's death has pleaded guilty to 10 crimes.

https://www.jacksonville.com/story/news/crime/2012/05/11/former-mayo-clinic-employee-pleads-guilty-spreading-hepatitis/15867187007/

MAYO CLINIC RESPONSE

The Gold Standard

- Created D-Dirt, the Drug Diversion Intervention and Response Team led by a special diversion coordinator.
- Have a zero tolerance policy
- Make friends with law enforcement
- Employ a 24-hour diversion hotline
- Employ a waste retrieval system
- Throw out assumptions about healthcare workers who divert drugs
- Know and keep track of areas
- Report it.
- Make sure hospital leaders understand
- Offer treatment once an employee is caught and terminated.

THE MAYO CLINIC RESPONSE
THE 77 BEST PRACTICE ELEMENTS

Controlled Substance Diversion, Detection and Prevention Program
Elements of Best Practice
(excluding Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
	Legend: CS-Controlled Substances; DEA-Drug Enforcement Administration; ADM-Automated Distribution Machine	
Tier 1 - Essential element and should be in place		
Tier 2 - Recommended element. Progress toward implementation should be made over time		
	CORE PRINCIPLES	
1	The chain of custody and individual accountability of Controlled Substances (CS) are maintained at all times.	1
2	Organizational policies exist that address all aspects of CS medication use processes. Policies are regularly reviewed and are compliant with federal and state regulations.	1
3	Organizational policies are adhered to by all staff.	1
	STORAGE & SECURITY	
4	CS are securely stored in a locked location (i.e. ADM, safe, locked cabinet/drawer) at all times unless in the direct physical control of an authorized individual.	1
5	CS that are under the control of an authorized individual are not placed where their view may be obscured or where a distraction may prevent direct observation at all times.	1
6	Access to CS storage areas is minimized and limited to authorized staff.	1
7	CS brought in by a patient that cannot be returned home are inventoried by two authorized healthcare staff, and stored in a locked, limited-access area.	1
	PROCUREMENT	
8	All CS are obtained from pharmacy.	1
9	Only authorized pharmacy staff can purchase CS.	1
10	The number of individuals authorized to order CS is minimized.	1
11	Separation of duties exist between the ordering and receipt of CS.	1
12	Two individuals count and check-in CS received and comfirm that order, invoice, and product-received documentation match.	1
13	CS inventory levels are based upon usage in order to minimize excess stock.	1
14	Automated CS safe technology is utilized.	1
15	Electronic CS Ordering System (CSOS) is utilized (eliminates paper DEA 222 forms).	1
16	A process is in place to identify unusual "peaks" in quantity or frequency of CS ordered.	2
17	All CS procurement paperwork is reviewed for completion and filed according to applicable laws and regulations.	1

https://web.archive.org/web/20220705153843/https://www.mayoclinicproceedings.org/cms/10.1016/j.mayocp.2012.03.013/attachment/968730c2-4b52-4bc4-9bf0-2ee56fa5532f/mmc1.pdf

MINNESOTA DOH SUMMARY

- SAFE – Safety teams, Access to information, facility expectations, educate staff
- Storage and security
- Procurement
- Prescribing
- Preparation & dispensing
- Administration of CS
- Handling CS waste
- Monitoring of CS & process if diversion is suspected

Road Map to Controlled Substance Diversion Prevention

https://www.health.state.mn.us/facilities/patientsafety/drugdiversion/docs/divroadmap041812.pdf

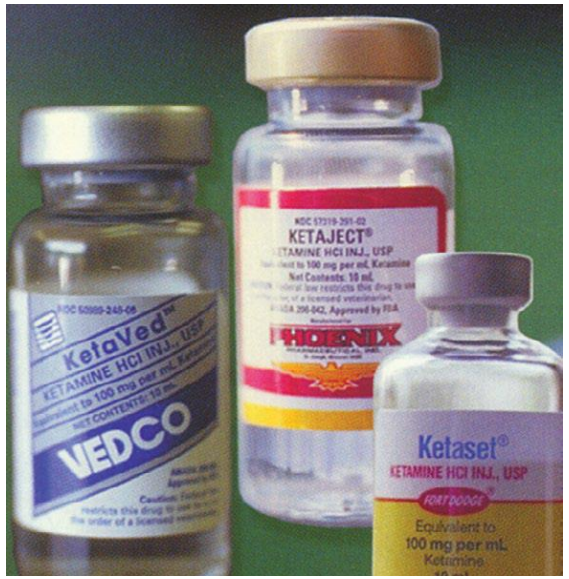
OTHER UPDATES & DEA RESOURCES

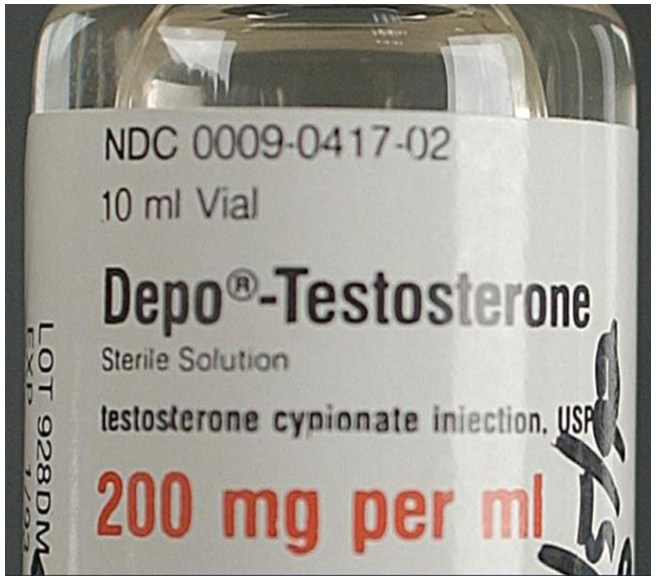
NATIONWIDE OPIOID SETTLEMENTS UPDATE

https://nationalopioidsettlement.com/wp-content/uploads/2022/03/Final_Distributor_Settlement_Agreement_3.25.22_Final.pdf Appendix P
https://nationalopioidsettlement.com/wp-content/uploads/2023/10/2023.10.13-Updated-Walgreens-Multistate-Settlement-Agreement.pdf Exhibit P
https://nationalopioidsettlement.com/wp-content/uploads/2023/10/Walmart-Settlement-Agreement-2023.10.18.pdf Exhibit P
https://nationalopioidsettlement.com/wp-content/uploads/2023/10/2023-12-09-CVS-Global-Opioid-Settlement-Agreement-with-2023-02-03-Technical-Corrections-and-2023-09-29-Updates.pdf Exhibit P

KETAMINE THERAPY INFUSIONS/IM'S & TESTOSTERONE INJECTIONS/PELLETS

Both require recordkeeping & security





https://www.dea.gov/factsheets/ketamine
https://www.dea.gov/sites/default/files/2022-12/2022_DOA_eBook_File_Final.pdf
https://www.dea.gov/galleries/drug-images/steroids

DEA REGISTRATION & MORE ASSISTANCE

HQ Registration Call Center

- (800) 882-9539
  8:30 am-5:50 pm EST
  DEA.Registration.Help@usdoj.gov

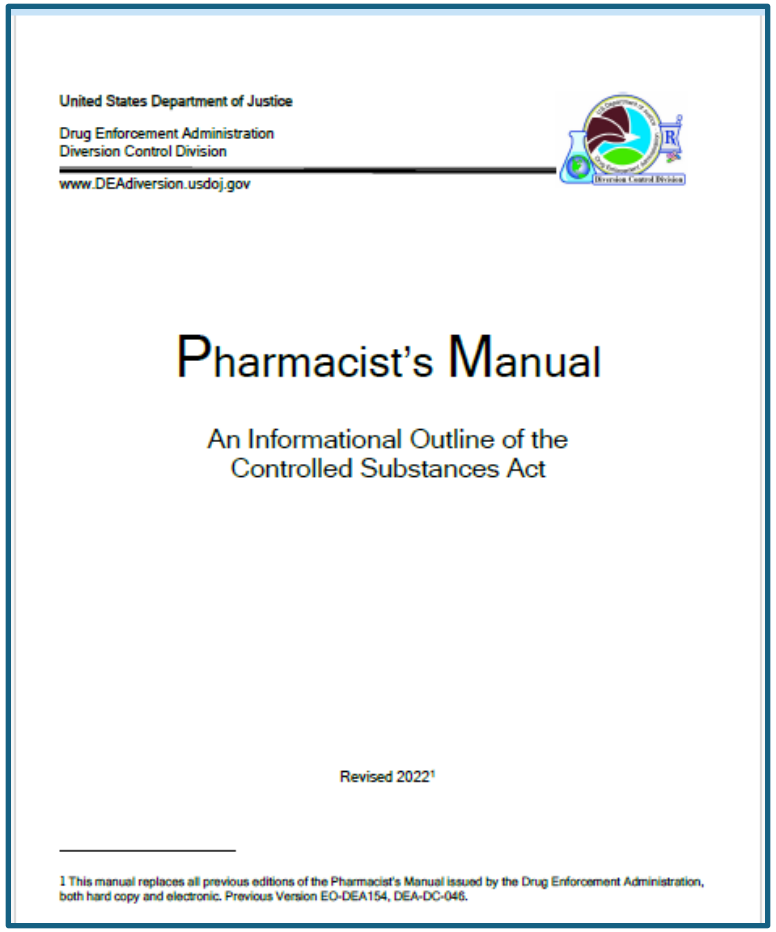
- ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES
  EPCS@usdoj.gov

- INTERPRETATION AND GUIDANCE ON DEA POLICIES AND REGULATIONS
  DPY@usdoj.gov

- COMPLAINTS & OTHER INQUIRIES
  ODLL@DEA.GOV

- General Inquiries
  DiversionHQ.Outreach@dea.gov

NEW UPDATED PHARMACIST'S MANUAL (2022)



United States Department of Justice

Drug Enforcement Administration
Diversion Control Division

www.DEAdiversion.usdoj.gov

Pharmacist's Manual

An Informational Outline of the
Controlled Substances Act

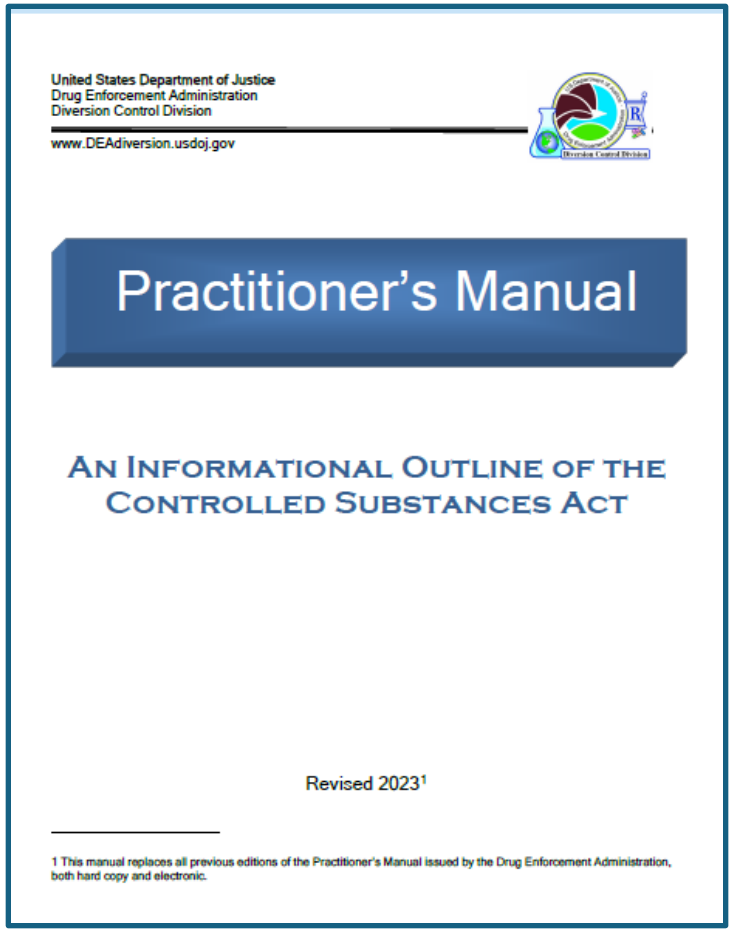
Revised 2022[1]

1 This manual replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic. Previous Version EO-DEA154, DEA-DC-046.

- Easy to read
- Closest manual to ASC operations
- References all of the drug recordkeeping requirements - pages 34 & 35

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist's_Manual_DEA.pdf

NEW UPDATED PRACTITIONER'S MANUAL (2023)


United States Department of Justice
Drug Enforcement Administration
Diversion Control Division

www.DEAdiversion.usdoj.gov

Practitioner's Manual

AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT

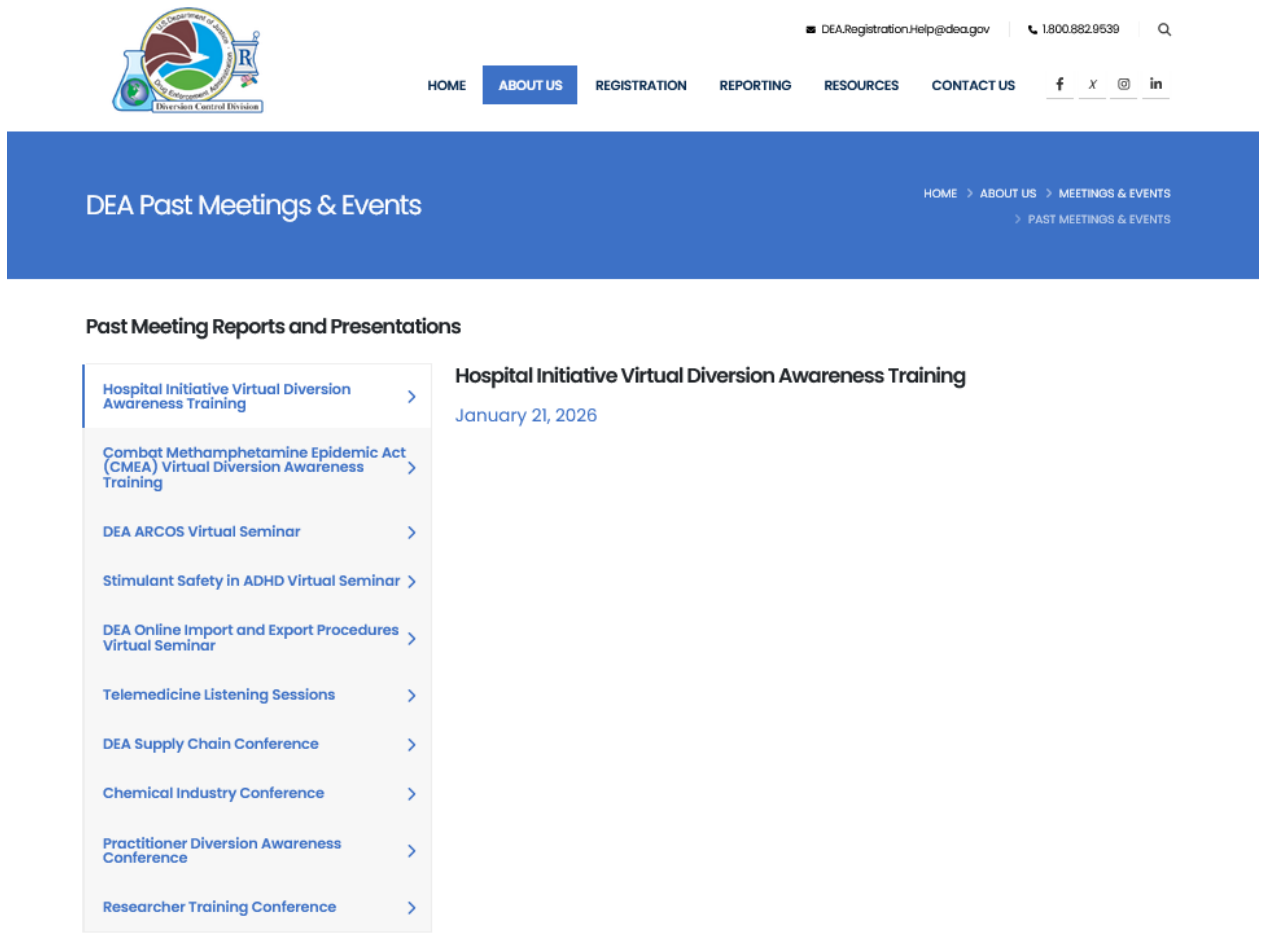
Revised 2023[1]

1 This manual replaces all previous editions of the Practitioner's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

- Easy to read with links
- Not as detailed as Pharmacist's Manual but linked to CFR

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf

DEA CONFERENCES & TRAINING SLIDE DECKS



https://www.deadiversion.usdoj.gov/mtgs/past-meetings.html

OTHER ONLINE DEA RESOURCES

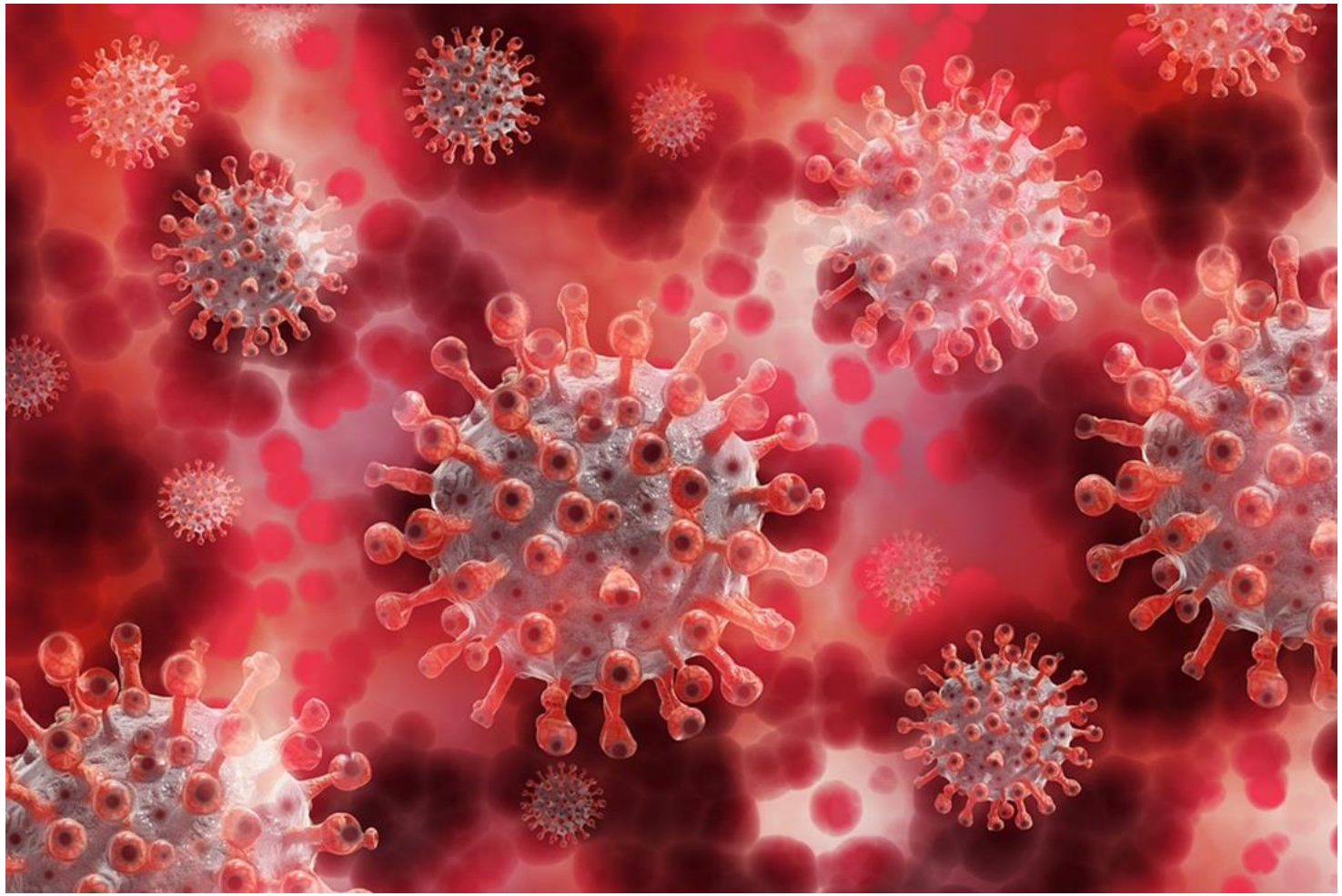
HTTPS://WWW.DEADIVERSION.USDOJ.GOV/

https://www.deadiversion.usdoj.gov/disaster_relief.htm

https://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html

https://apps.deadiversion.usdoj.gov/pubdispsearch

TELEMEDICINE & COVID



"DEA ANNOUNCES PROPOSED RULES FOR PERMANENT TELEMEDICINE FLEXIBILITIES"

10/15/2008 – Congress Passes Ryan Haight Act (requires in-person visit).

1/31/2020 – HHS issues "Public Health Emergency (PHE)" (allows for multiple healthcare and telemedicine exemptions).

1/31/2023 – President Biden announces end of PHE on 5/11/2023.

2/24/2023 – DEA & HHS announce new proposed telemedicine flexibilities regulations (38,000 public comments).

5/11/2023 – HHS PHE ends.

12/31/25 - Exception extended until 12/31/2026

https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities
https://www.dea.gov/sites/default/files/2023-02/Telemedicine%20%28DEA407%29.pdf
https://admin.dea.gov/sites/default/files/2023-02/Expansion%20of%20Bup%20%28DEA948%29.pdf
https://www.dea.gov/sites/default/files/2023-02/Telemedicine%20Rules%20Summary.pdf
https://www.dea.gov/sites/default/files/2023-02/Telehealth_Practitioner_Narrative.pdf
https://www.dea.gov/documents/2023/2023-10/2023-10-06/dea-and-hhs-extend-telemedicine-flexibilities-through-2024
https://www.dea.gov/press-releases/2025/12/31/dea-extends-telemedicine-flexibilities-ensure-continued-access-care

WRAP IT UP

SAFEGUARDS & RISK MITIGATION FOR FACILITIES

- Maintain robust security and recordkeeping for CS's
- Limit the locations and access to CS's
- Use the "rule of two" in high-risk situations – before and after use of opioid syringes
- Key threat – opioid syringes & vials
- Follow national/state/best practice guidelines whenever possible
- Practice due diligence & have a process/policies
- Never share passwords for CS ordering & prescribing
- Maintain a perpetual inventory and more?
- Keep meticulous records

QUESTIONS?

Dennis Wichern

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