DRUG ENFORCEMENT ADMINISTRATION
Liason & Outreach Section (DPL)

Hospital Diversion Updates from DEA Diversion Control

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I have no financial relationships to disclose.

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Speaker Introduction/Background

John Conner
Staff Coordinator
Drug Enforcement Administration
Diversion Control Division

Learning Objectives

- Closed System of Distribution
- Inspections
- Recordkeeping & Inventory Requirements
- Theft and Loss
- Security & Destruction
- Ordering Controlled Substances
- Trends to Look For

December 2025

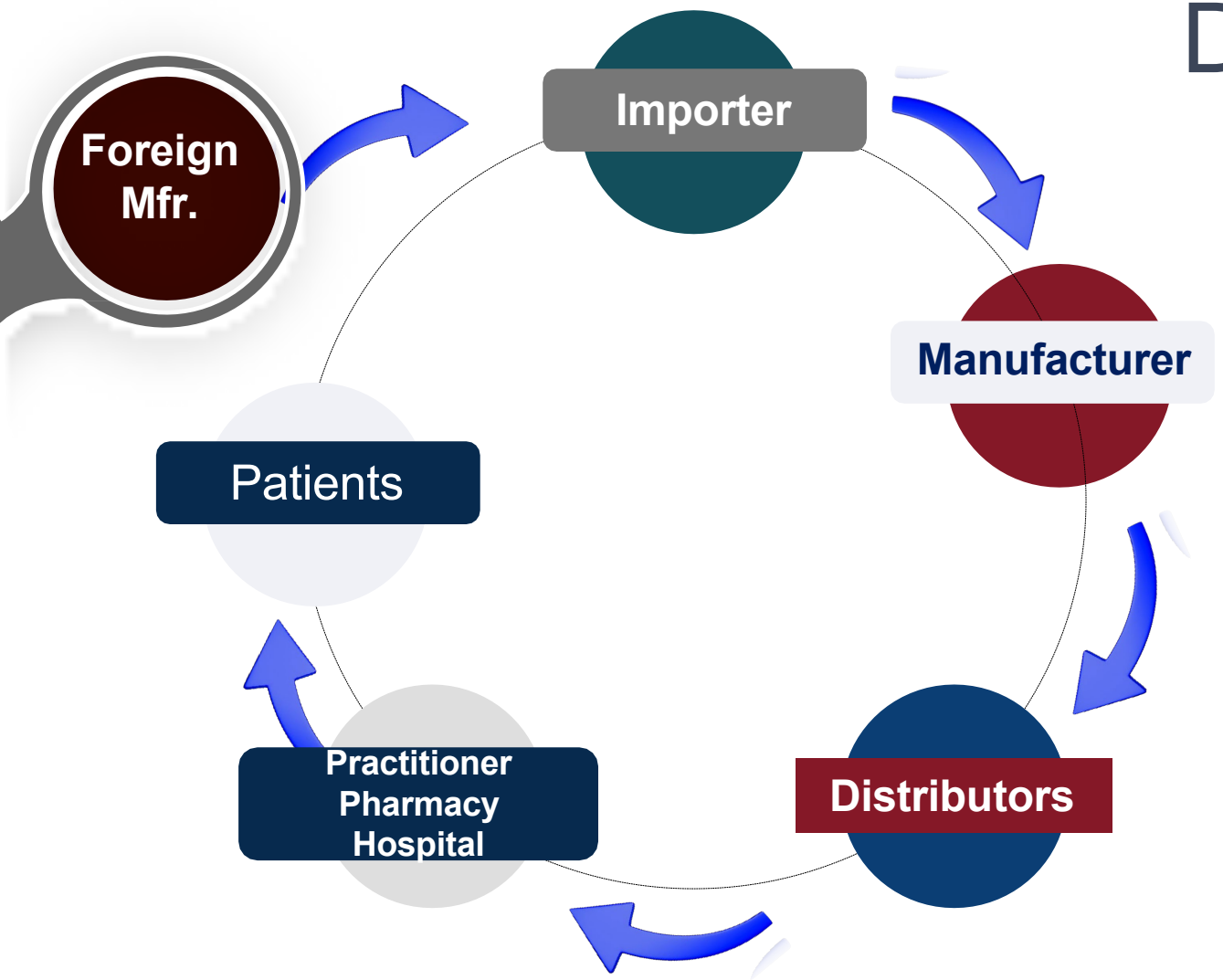
U.S. Department of Justice · Drug Enforcement Administration · Diversion Control Division

Diversion Control Division

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

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

Closed System of Distribution

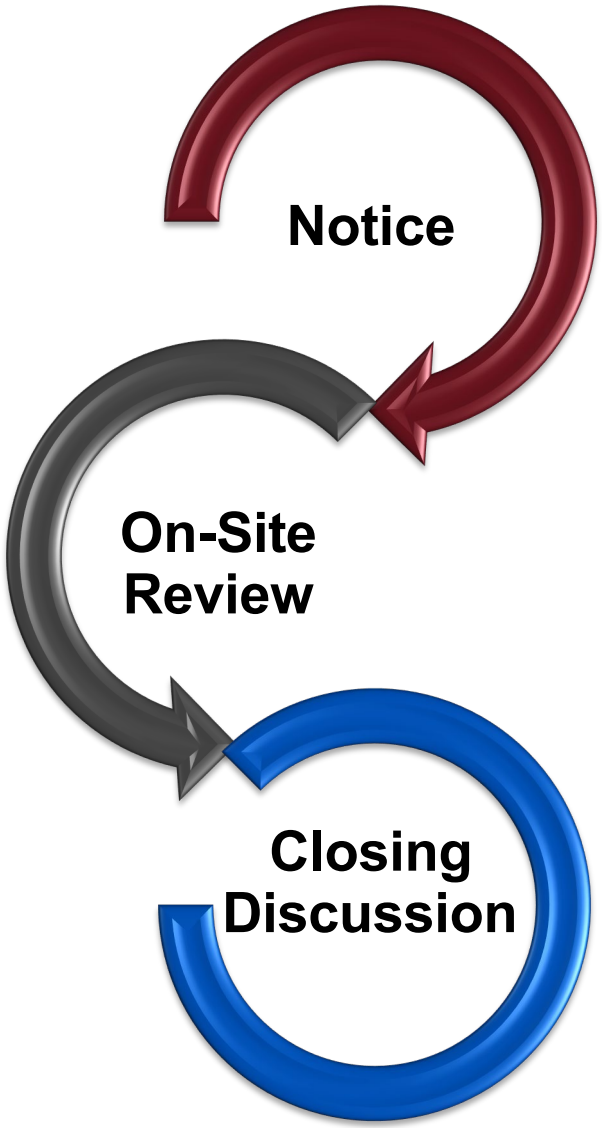


DEA is responsible for:

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

Oversight of Closed System of Distribution

Inspections



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

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

Security

Records & Inventories

Medical Records

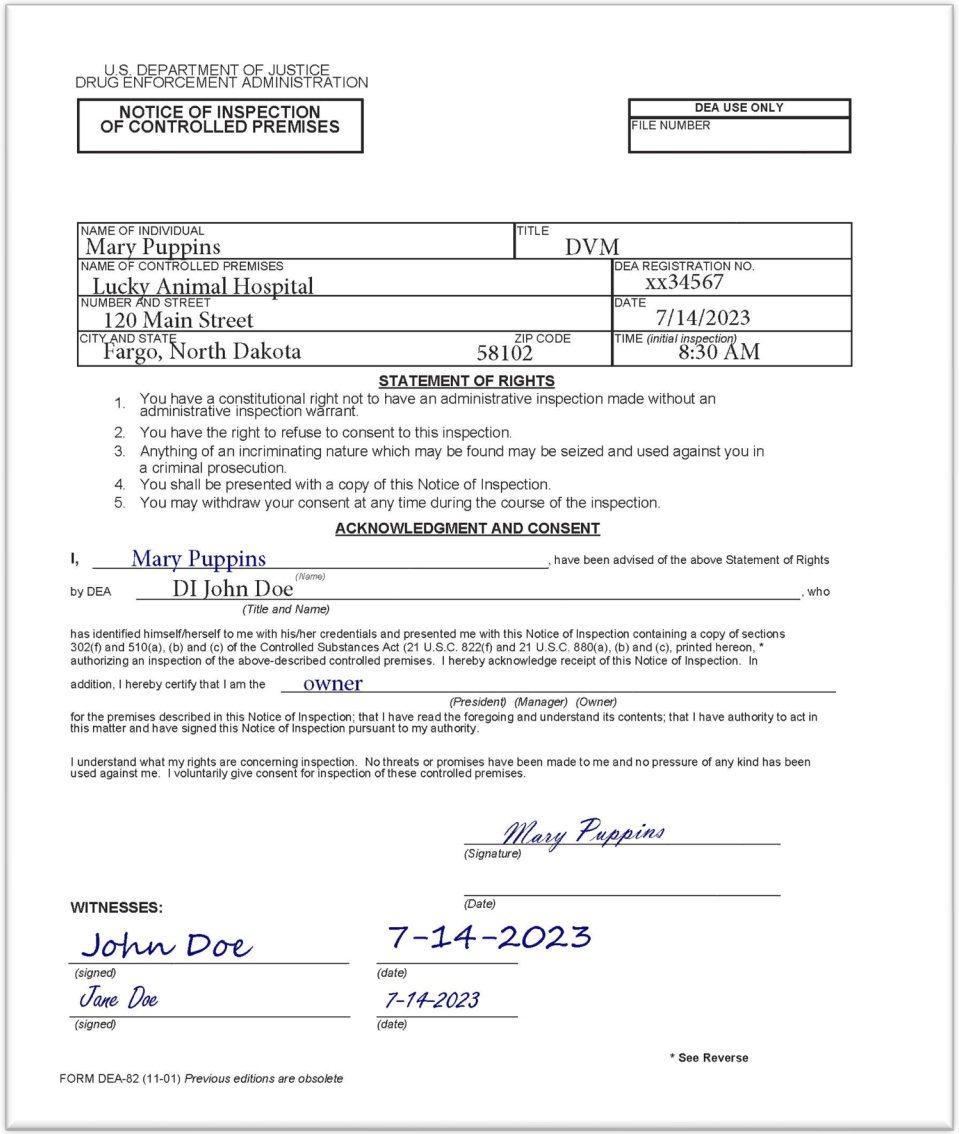
Drug Disposal/ Destruction

Licensing

Reporting

§1316.03 Authority to conduct inspections.

Inspection Procedures



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

NOTICE OF INSPECTION OF CONTROLLED PREMISES

DEA USE ONLY
FILE NUMBER

NAME OF INDIVIDUAL: Mary Puppins	TITLE: DVM
NAME OF CONTROLLED PREMISES: Lucky Animal Hospital	DEA REGISTRATION NO.: xx34567
NUMBER AND STREET: 120 Main Street	DATE: 7/14/2023
CITY AND STATE: Fargo, North Dakota ZIP CODE: 58102	TIME (initial inspection): 8:30 AM

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.

ACKNOWLEDGMENT AND CONSENT

I, Mary Puppins (Name), have been advised of the above Statement of Rights by DEA DI John Doe (Title and Name), who has identified himself/herself to me with his/her credentials and presented me with this Notice of Inspection containing a copy of sections 302(f) and 510(a), (b) and (c) of the Controlled Substances Act (21 U.S.C. 822(f) and 21 U.S.C. 880(a), (b) and (c), printed hereon, * authorizing an inspection of the above-described controlled premises. I hereby acknowledge receipt of this Notice of Inspection. In addition, I hereby certify that I am the owner (President) (Manager) (Owner) for the premises described in this Notice of Inspection; that I have read the foregoing and understand its contents; that I have authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.

I understand what my rights are concerning inspection. No threats or promises have been made to me and no pressure of any kind has been used against me. I voluntarily give consent for inspection of these controlled premises.

Mary Puppins (Signature)

(Date)

WITNESSES:

John Doe (signed) 7-14-2023 (date)

Jane Doe (signed) 7-14-2023 (date)

* See Reverse

FORM DEA-82 (11-01) *Previous editions are obsolete*

- Inspections are unannounced
- Diversion Investigators with credentials
- Will present “Notice of Inspection”
- Ask responsible employee for consent

Steps of an On-Site Inspection

- Meet with Registrant and controlled substance handler(s)
- Tour of Facility: Specifically, where controlled substances are stored
- Discussions of Standard Operation Procedures (SOPs)
- Review Records
- Physical count of Controlled Substances on hand
- Closing Meeting with management

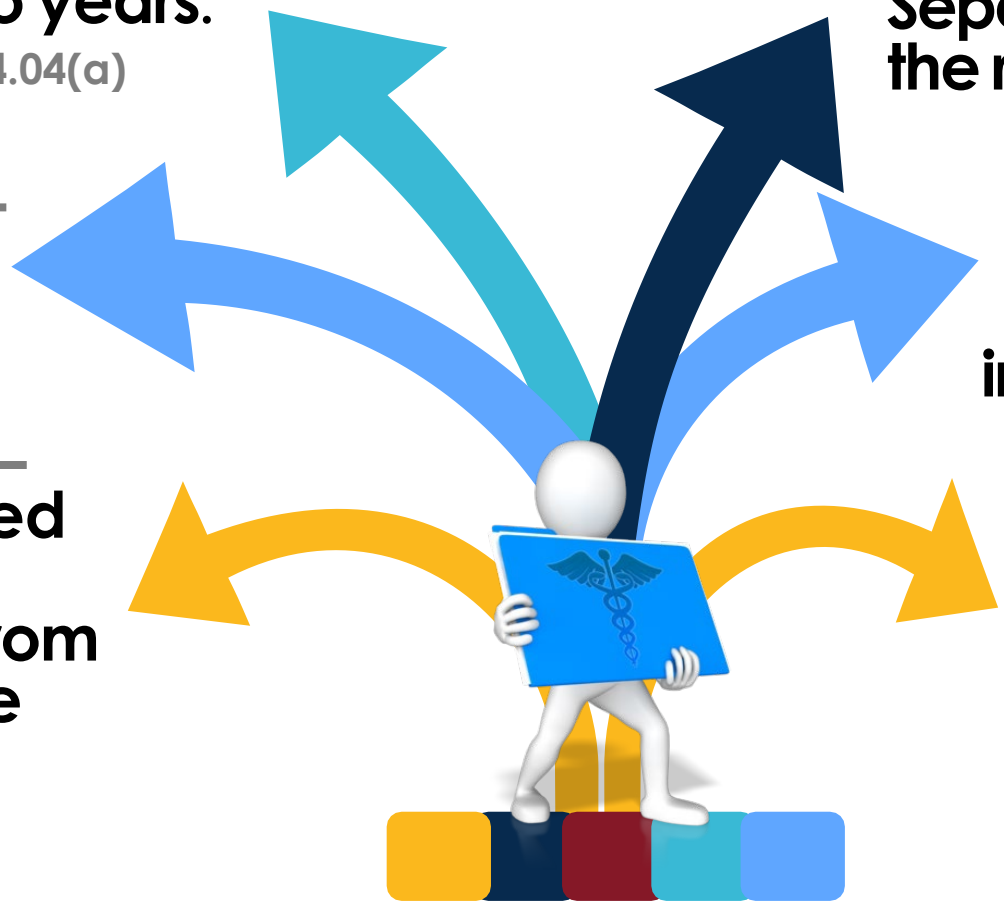
General Requirements

CONTINUING RECORDS

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

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

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



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

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

Complete and accurate.
21 CFR 1304.21(a)

DEA Required Record Keeping

- CSA created a closed system of distribution.
  Must keep records for at least two years.
- Record all administrations/dispensations.
- If recorded in patient files, those files must be made available for DEA inspection.
- All inventories and records of Scheduled II controlled substances must be kept *separate* from all other records at registered location.

Inventory

Taken at least every two years “21 CFR 1304.04(a)”

All stocks of controlled substances on hand (including samples)

Physical inventory must include:

- Schedule II on a separate inventory from Schedule III-V “21 CFR 1304.04(g)”
- The date/time the inventory is taken (BOB/COB)
- Kept for at least 2 years at the registered location “21 CFR 1304.11”

Items Requested During Inspection

- List of Employees with Access to Controlled Substances (Name, Title, Address, DOB)
- Copies of Licenses and Certificates (other federal/state)
- Facility Floor Plan
- Receiving Records (222s, Invoices/purchase orders/ packing slips, CSOS)
- Power of Attorney to order CIIs
- 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 (or initial inventory)
- Copy of alarm company contract
- List of Suppliers (Name, address, DEA #)

Controlled Substances Accountability Audit



Includes all locations:

- Automated Dispensing Machines
- Med Carts
- Safes/Vaults
- Disposal/Expired

Controlled Substance Audit Procedures

Investigators will ask for and review all controlled substance records to perform an audit

Investigators witness a physical count conducted by you, the registrant, using your records

Investigators will audit several controlled substances, from different Schedules, over a predetermined period of time

If the audit reveals discrepancies, this could be an indication of incomplete and inaccurate recordkeeping practices and/or diversion

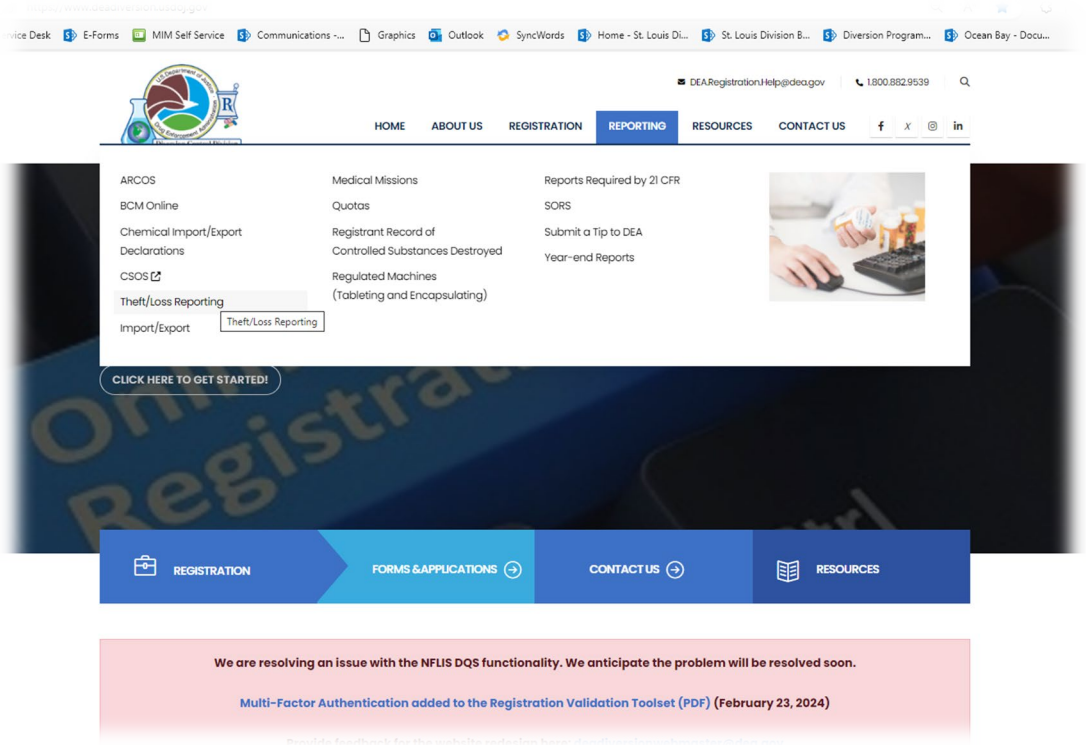
The audit indicates whether controlled substance records were complete, thus "maintained effective controls against diversion."

Theft and Loss Reporting

Must report a theft or significant loss to DEA in writing **within one business day**

Must complete a **DEA Form 106 within 45 days**, online

Registrants also encouraged to report theft and losses to local law enforcement and state regulatory agencies



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 of Controlled Substances Form 106

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

1. Name and Address of Registrant [redacted]		**Amendment Key / Date Submitted** [redacted] / 2022-05-03 18:32
3. DEA Registration Number [redacted]	**4. Date of Theft / Loss** 2022-04-27 Amendment # 1 [0] [1]	**5. Registrant's Principal Business** RETAIL PHARMACY
6. Registrant's County MARICOPA	**7. Theft Reported to Police?** Y	**8. Dept. 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]

Security Procedures

Investigators will inspect overall security procedures and components to ensure that “effective controls to guard against theft and diversion” are met.

Security

REQUIREMENTS

- Provide effective controls and procedures to guard against theft and diversion of controlled substances.

  21 CFR 1301.71(a)

- Cannot employ anyone who has a felony drug conviction who will have access to controlled substances, without a DEA approved employment waiver.

  21 CFR 1301.76(a)

- Store stocks of CII-CV controlled substances in a securely locked, substantially constructed cabinet.

  21 CFR 1301.75(b)

BEST PRACTICES

- Safe
- Alarm System
- Camera System
- Limit Access to Controlled Substances (including waste)

Disposal of Controlled Substance Inventory

Title 21 Code of Federal Regulations- PART 1317 — DISPOSAL

OPTIONS TO DISPOSE OF

21 CFR 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 CFR 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

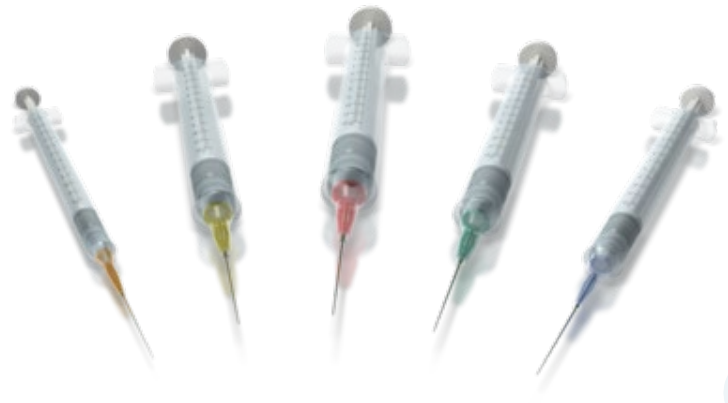
21 CFR 1317.05(a) (4)

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 (hospital or clinic)

21 CFR 1304.21(e)



Disposal of Controlled Substances

Registrants authorized to collect and authorized collection activities
21 CFR 1317.40

Authorized Collectors

Collection by registrants shall occur only at the following locations:
(1) Those registered locations of manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that are authorized for collection; and
(2) Long-term care facilities at which registered hospitals/clinics or retail pharmacies are authorized to maintain collection receptacles.

Individual practitioners, such as medical doctors, dentists, or veterinarians are not authorized to be collectors.

Post-Inspection

- Investigators will meet with the registrant to explain the results of the inspection.
- Investigators will advise the registrant what must be done to comply with the CSA and its regulations.

Potential Adverse Actions

- Letter of Admonition
- Civil Fines
- Memorandum of Agreement
- Order to Show Cause
- Immediate Suspension Order
- Criminal Prosecution

Registrant Inspections - Common Findings

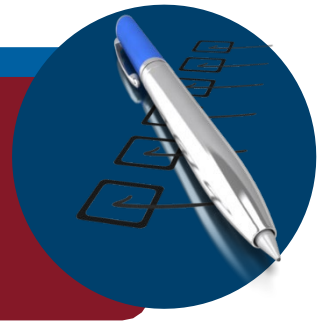
- Lack of knowledge of software
- Dispensing logs not maintained
- Execution of DEA Form 222
- Lack of required physical inventories such as initial and biennial inventories
- No spill log (manual)
- Spill log (electronic) not accurate
- No checks and balances regarding spills
- Not properly reconciling
- 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

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

DEA Form-222- Official Order Forms - 21 CFR 1305

- The DEA Form -222 is used for the distribution of Schedule I and II controlled substances **21 CFR 1305.03**

- The DEA Form-222 must be filled out completely and accurately **21 CFR 1305.13**

- Power of Attorney authorizing who may execute a DEA Form-222 **21 CFR 1305.05**

DEA Form 222 Official Order Form

DEA FORM-222

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION

OMB APPROVAL No. 1117-0010

PURCHASER INFORMATION

REGISTRATION INFORMATION

REGISTRATION #:
REGISTERED AS:

SCHEDULES:
ORDER FORM NUMBER:
DATE ISSUED:

SUPPLIER DEA NUMBER:#

PART 2: TO BE FILLED IN BY PURCHASER

BUSINESS NAME

STREET ADDRESS

CITY, STATE, ZIP CODE

PART 1: TO BE FILLED IN BY PURCHASER

Print or Type Name and Title

Signature of Requesting Official (must be authorized to sign order form) Date

PART 5: TO BE FILLED IN BY PURCHASER

PART 3: ALTERNATE SUPPLIER IDENTIFICATION - to be filled in by first supplier (name in part 2) if order is endorsed to another supplier to fill.

ALTERNATE DEA #

Signature- by first supplier

OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER DATE

ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE	NUMBER SHIPPED	DATE SHIPPED
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
	← LAST LINE COMPLETED (MUST BE 20 OR LESS)							

Ordering Schedules III-V Controlled Substances

Keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate.

21 CFR 1304.21(a) & (d)

Receipts must also contain the following information:

21 CFR 1304.22(c), 1304.22(a)(2)

- Name of the substance
- Must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers ordered and received.
- Must contain details of each registrant's DEA #, name, address.

Controlled Substance Ordering System (CSOS) Electronic Order Forms

- Only allowance for the electronic transmission of Schedule II Controlled Substance orders between controlled substance manufacturers, distributors, pharmacies, and other DEA authorized entities.
- Users must obtain a CSOS digital certificate for electronic ordering.
- Electronic orders must be signed **using a digital signature** issued by a Certification Authority (CA) run by the DEA.

Transfer of Controlled Substances

What if I need to transfer controlled substances to another DEA registrant?

- Use a sales invoice for Schedules III-V - **21 CFR 1307.11 (a)(1)(ii)**
- Use a DEA Form-222 (C I & II) - **21 CFR 1307.11(a)(1)(iii)**
- Only allowed 5% of your yearly total - **21 CFR 1307.11(a)(1)(iv)**
- If you do more than 5%, you must register with DEA as a distributor - **21 CFR 1307.11(b)**

Dispensing

- **Dispenser**: An individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance: "21 CFR 1300.01 (b)"

- DEA number for each location if dispensing/administering: "21 CFR 1301.12 (a)"

- Only one DEA number needed per state if only prescribing: "21 CFR 1301.12 (b)(3)" (Some COVID flexibilities, please see www.deadiversion.usdoj.gov for latest COVID policies)

Dispensing / Administration

Administer / Dispensing Records "21 CFR 1304.22 (c)"

Recommend a log is kept, but can be in a patient chart

Required:

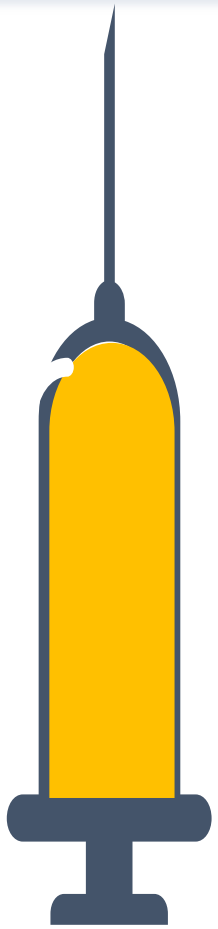
1) Name of Substance
2) Strength
3) Quantity
4) Patient name
5) Patient address
6) Date
7) Written or typed name or initials of the individual who dispensed or administered the substance on behalf of the dispenser

Trends to Watch For

Diversion Affects All

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

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



Hospitals bear the cost of diverted drugs, internal investigations, civil fines and negative reputation

Community suffers though contributory drug misuse and mistrust in healthcare

Misused Controlled Prescription Drugs

Figure 51. Top 10 Misused controlled prescription drugs, Self-reported to National Survey on Drug Use and Health

CPD	Common or Trademark Name*	Category
Hydrocodone Products	Hycodan, Lorcet-HD, Lortab, Vicodin, Vicoprofen	Pain Reliever
Amphetamine Products	Adderall, Dexedrine, Vyvanse	Stimulant
Oxycodone Products	Endocet, OxyContin, Percocet, Percodan, Roxicet, Roxicodone	Pain Reliever
Alprazolam Products	Xanax	Tranquilizer
Codeine Products	Methyl morphine, Promethazine with codeine	Pain Reliever
Tramadol Products	Conzip, Tramadol, Ultram, Ultram Er	Pain Reliever
Clonazepam Products	Clonopin, Klonopin	Tranquilizer
Zolpidem	Ambien, Ivadal, Stilnoct, Stilnox	Sedative
Buprenorphine Products	Buprenex, Suboxone, Subutex, Temgesic	Pain Reliever, Opioid Dependence (Treatment)
Lorazepam Products	Ativan	Tranquilizer

**Most of these substances come in generic forms*

Source: National Survey on Drug Use and Health (2023), DEA Drugs of Abuse (2022 Edition)

Warning Signs: Health Care Professionals

Practitioners who:

- Prescribe or dispense controlled substances that are not medically justified
- Perform minimal and/or no medical evaluations
- Do not follow standard medical guidelines
- Share a token and/or credentials

Warning Signs: Patients

- Doctor shoppers (Use the PDMP)
- Early refill request at hospital pharmacy
- Specific type of medication request
- Frequently reports loss of medication at hospital pharmacy
- Drastic increase in pain level

Fraudulent electronic prescribing increasing

DEA observed an increase in fraudulent electronic prescriptions (e-scripts) between 2021 and 2023.

DEA registrants are reporting fraudulent use of their registration numbers and identities on prescriptions submitted via e-script in locations across the country.

The further expansion of online telehealth services and e-script portals during the COVID-19 pandemic presented increased opportunities for e-script abuse by patients or office staff, and through identity theft.

Telemedicine

DEA, SAMHSA Extend COVID-19 Telemedicine Flexibilities for Prescribing Controlled Medications for Six Months While Considering Comments from the Public

- The temporary rule took effect on May 11, 2023, **and extends the full set of telemedicine flexibilities adopted during the COVID-19 public health emergency through December 31, 2026**
- For any practitioner-patient **telemedicine relationships that have been or will be established up to December 31, 2026**, the full set of telemedicine flexibilities regarding prescribing of controlled medications established during the COVID-19 PHE will be **extended for one year – through December 31, 2026**

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

What Can You Do?

If you SEE Something…
SAY Something

Report suspicious behavior from:

- ✓ Practitioners
- ✓ Employees
- ✓ Peers/Co-workers
- ✓ Patients/Pet Owners

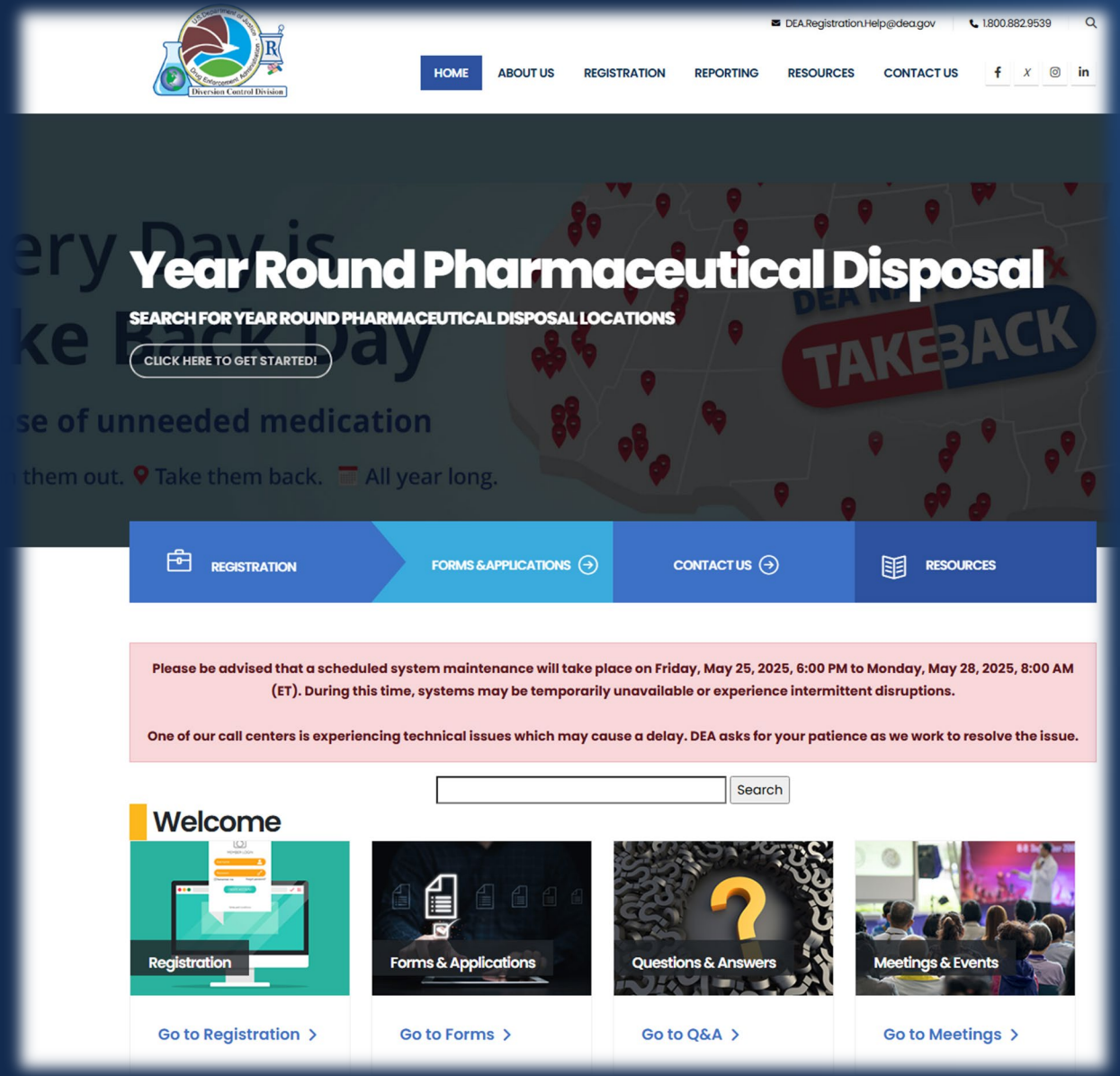
Help STOP Diversion of Prescription Medications

Anyone with information about suspected controlled substance diversion should report that to the Drug Enforcement Administration via our website DEAdeadiversion.usdoj.gov, or contact the DEA hotline at **1-877-792-2873** or your local DEA field office.

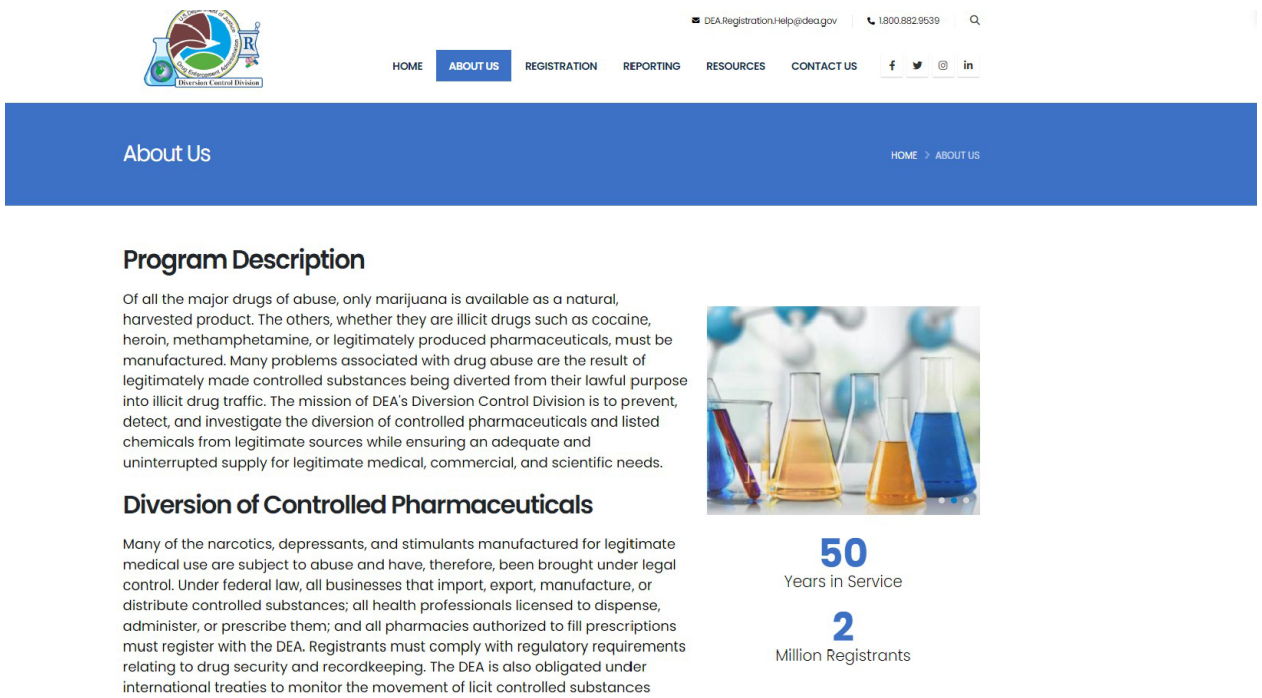
SCAM ALERT

- DEA Imposter?
  ReportFraud.ftc.gov
- Internet Crime Complaint?
  ic3.gov
- Call local DEA Diversion Group

DEA Resources



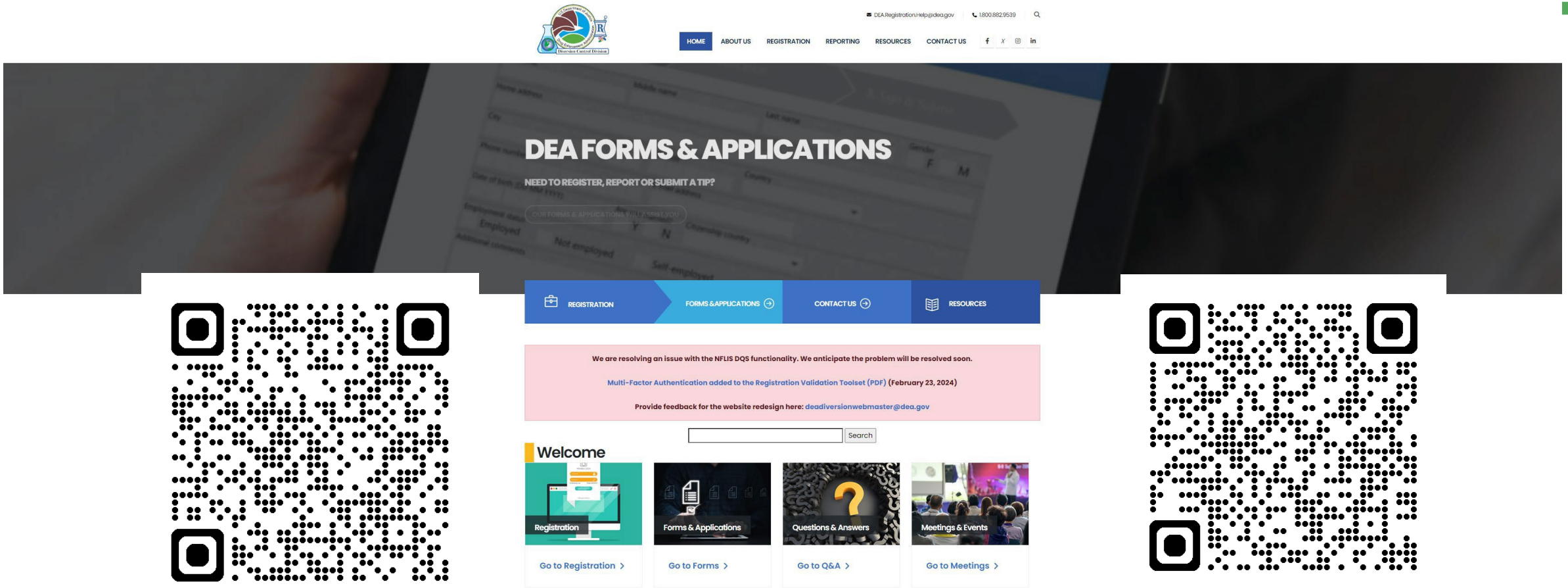
RESOURCES FOR HEALTHCARE PROFESSIONALS



Pharmacist's Manual

WWW.DEADIVERSION.USDOJ.GOV
(go to Resources – Publications & Manuals)

DEA Registration Resources



Diversion Control Division | Welcome (usdoj.gov)

eCFR :: Home

RESOURCES: DEADiversion.usdoj.gov

DEA.Registration.Help@dea.gov | 1.800.882.9539

HOME | ABOUT US | REGISTRATION | REPORTING | RESOURCES | CONTACT US

Obtain or Renew DEA Registration

Save Time, Apply Online

CLICK HERE TO GET STARTED!

1.800.882.9539

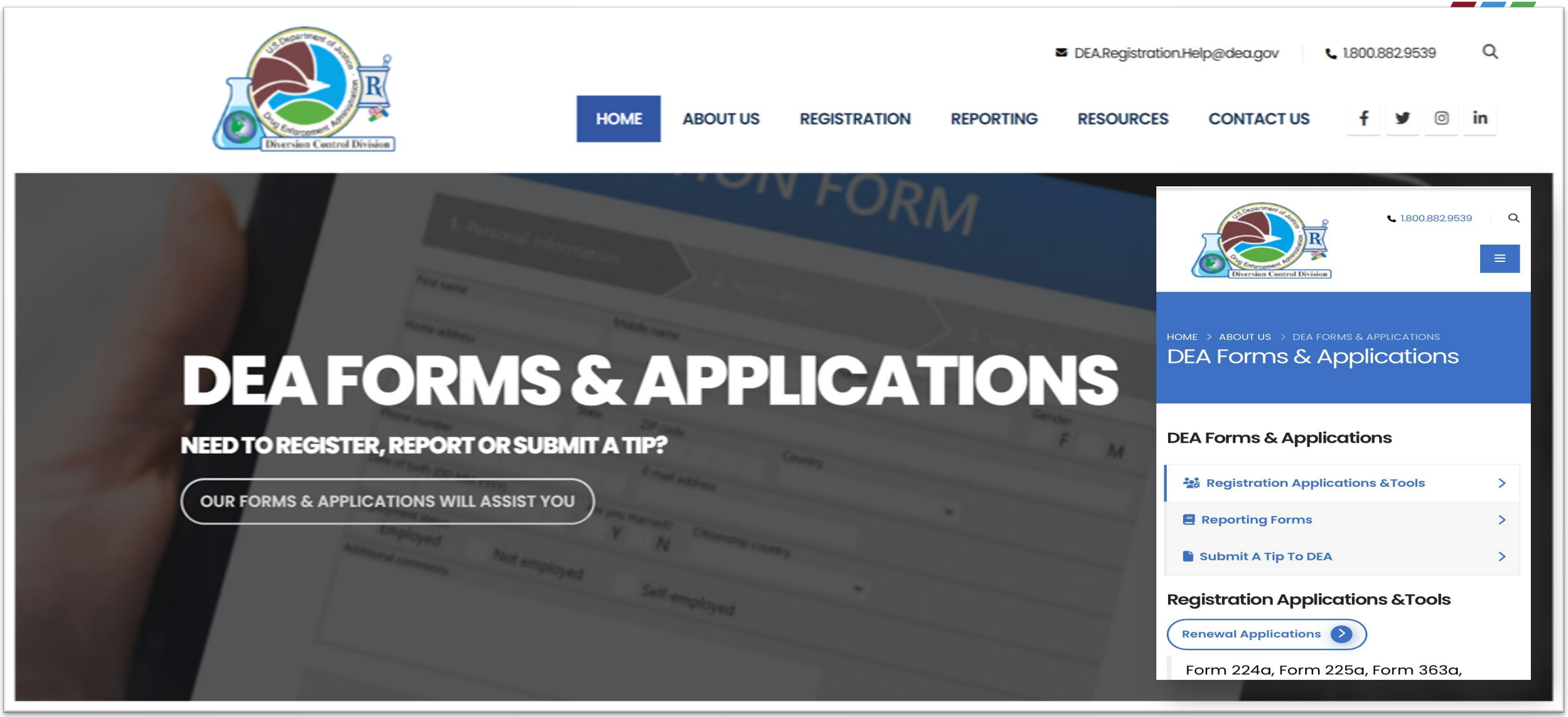
HOME > REGISTRATIONS

Registration

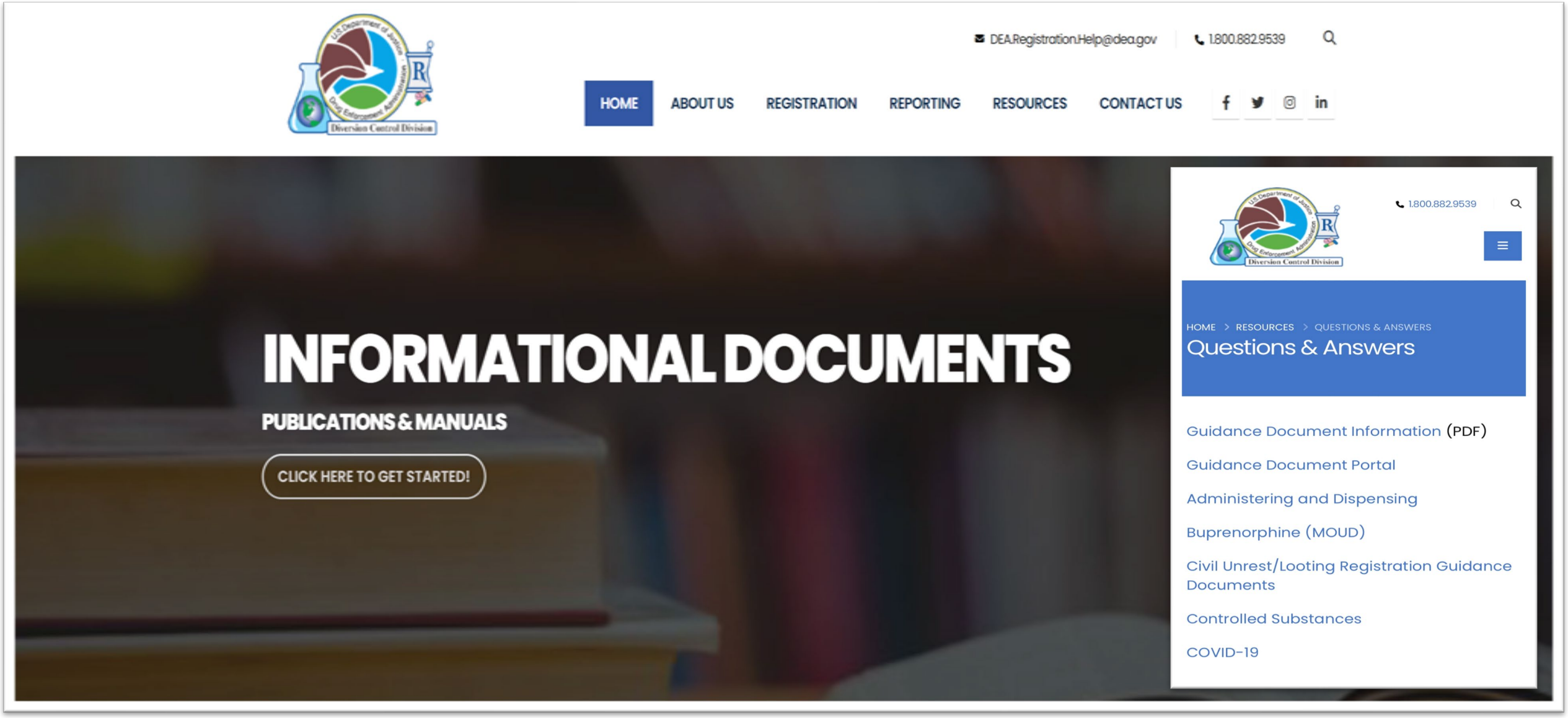
Registration Applications, Tools and Resources

- Renewal Applications
- New Applications
- Make Changes to My DEA Registration
- Check Status of DEA Registration Application
- Request Copy of DEA Certificate

RESOURCES: DEADiversion.usdoj.gov



RESOURCES: DEADiversion.usdoj.gov



THANK YOU!!!!

Questions?

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