



Supply Chain Conference 2023

Registrations



May 2023



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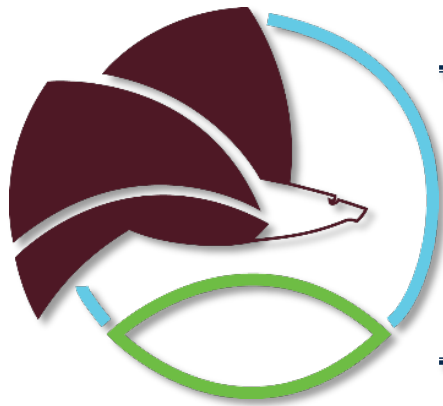
I have no financial relationship to disclose.





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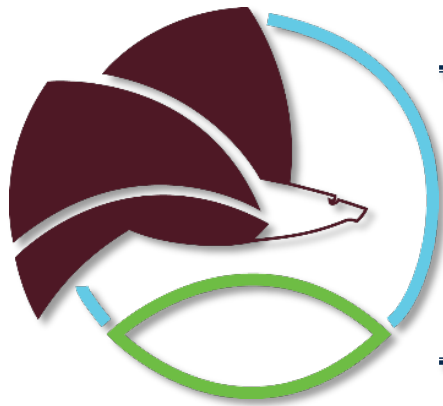
Topics that will be Covered





- **Registration and Program Support Section (DRR)**
- **Persons required to register**
- **How to Register**
- **Common Questions**
- **Common Problems Encountered**
- **Assistance with Registration Matters**





***Who is the Diversion
Registration Section***



Registration and Program Support Section (DRR)



- DRR is responsible for all registration programs and activities managed by the Diversion Control Program.
- DRR provides registration guidance and assistance to the field's 75+ Registration Program Specialists (RPS).
- DRR ensures registrant databases are maintained appropriately, conducts quality control and verification of data, and provides management with reports and recommendations regarding registration activities and registrant information for more than two million registrants.





Units within DRR

- Registration Processing Operations Unit
- Registration Customer Response Unit
- Registration Business Unit
- Registration Call Centers
- Controlled Substance Ordering System Unit
- Registration Financial and Data Entry Unit



Registration and Program Support Section (DRR)



Registrant Population: 04/03/2023



BUSINESS ACTIVITY	REGISTRANT POPULATION
PHYSICIANS	1,394,320
MID LEVEL PRACTITIONER (MLP)	541,549
PHARMACY	69,807
HOSPITAL/CLINIC	19,235
TEACHING INSTITUTION	256
MANUFACTURING	582
DISTRIBUTOR	645
CANINE HANDLERS	3,004
RESEARCHER (I)	834
RESEARCHER (II-IV)	8,364
ANALYTICAL LAB	1,551
IMPORTER	273
EXPORTER	273
REVERSE DISTRIBUTOR	76
NARCOTIC TREATMENT PROGRAM (NTP)	2,178
CHEMICAL	
MANUFACTURING	220
IMPORTER	221
DISTRIBUTOR	318
EXPORTER	160
GRAND TOTAL:	2,043,866

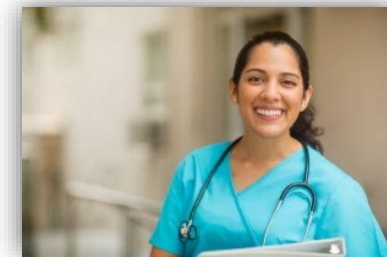
Total Registrant Population = 2,043,866



Registration and Program Support Section (DRR)



- **Registrant** is a term used to describe an individual or business entity that holds a DEA registration number authorizing the handling of controlled substances and/or List 1 chemical products.
- Combined, they are referred to as the *regulated community*.





Persons Required to Register





As stated in 21 USC –

- 822(a)(1): “Every person who manufactures or distributes any controlled substance or List I chemical ... shall obtain annually a registration ...”
- 822(b): “Persons registered ... to manufacture, distribute, or dispense controlled substances or List I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals...”



Persons Required to Register

(21 C.F.R. Section 1301.11(a))



21 CFR § 1301.11 Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy.

- (a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)



Persons Required to Register

(21 C.F.R. Section 1301.13(a))



21 CFR § 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

- **(a)** Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.





How to Register





Controlled Substances Applications:

224 New & 224A Renewal

- Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner

225 New & 225A Renewal

- Manufacturer, Distributor, Researcher, Canine Handler, Analytical Laboratory, Importer, Exporter

363 New & 363A Renewal

- Narcotic Treatment Program

Domestic Chemical Applications (List I Chemicals):

510 New & 510A Renewal

- Chemical Manufacturer, Chemical Importer, Chemical Exporter, Chemical Distributor



Registration Applications



All registrations must be submitted online via the DEA Diversion website at: www.DEAdiversion.usdoj.gov

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

HOME REGISTRATION REPORTING RESOURCES ABOUT US

REGISTRATION

REGISTRATION Get Email Updates:

NOTICES:

- Please note Registration Fee Increases Effective October 1, 2020.
- Effective September 1, 2016; Web Browsers and Systems are now Required to Support TLS 1.2
- **ALERT: Faxed-based phishing scams targeting Pharmacies**
- For security purposes we are no longer compatible with Microsoft Internet Explorer 8 or earlier versions. To ensure optimal experience the DEA recommends using Internet Explorer 9 or newer, Microsoft Edge, or the current versions of Mozilla Firefox, Google Chrome, or Apple Safari.

Renewal Applications

REVISED ANNOUNCEMENT REGARDING RENEWAL APPLICATIONS

Starting January 2017, DEA will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

At this time, DEA will otherwise retain its current policy and procedures with respect to renewal and reinstatement of registration. This policy is as follows:

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

DEA Form 224a – Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner

DEA Form 225a – Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, Exporter

DEA Form 363a – Narcotic Treatment Programs

DEA Form 510a – Domestic Chemical

New Applications

DEA Form 224 – Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution, or Mid-Level Practitioner

DEA Form 225 – Manufacturer, Distributor, Researcher, Canine Handler, Analytical Laboratory, Importer, Exporter

DEA Form 363 – Narcotic Treatment Programs

DEA Form 510 – Domestic Chemical

[Check the Status of My Application](#)

Applications
Tools
Resources
CEA Required Training & Self-Certification
Quota Applications
Notice of Registration

New Applications



CSA Registration Online Mgmt Tools: NEW Registration

Application for Registration Under Controlled Substances Act of 1970 (New Applicants Only)

ON-LINE REGISTRATION CONSISTS OF SIX (6) SECTIONS. Please have the following information available before you begin the application:

Section 1. Personal/Business Information

If you are applying for an Individual Registration (Practitioner, MLP, Researcher) you are required to provide your Full Name, Address, Social Security Number, and Phone Number. If you are applying for a Business Registration, you are required to provide the Name of the Business, Address, Tax ID, and Phone Number.

Section 2. Activity

Business Activity and Drug Schedule information. In addition - Certain registrants for forms 225 and 510 will need to provide specific drug codes and/or chemical codes related to their operations.

Section 3. State License(s)

It is mandatory to provide State medical and/or controlled substance licenses/registrations. For mid-level practitioners, this includes supervisory agreements, with specific authority for controlled substances, if required by your state. Failure to provide VALID and ACTIVE state licenses will be cause to declare the application as defective and it will be withdrawn WITHOUT refund.

Section 4. Background Information

Information pertaining to controlled substances in the applicant's background.

Section 5. Payment

Payment, via this on-line application, must be made with a Visa or MasterCard, American Express, or Discover. Application fees are not refundable.

Section 6. Confirmation

Applicants will confirm the entered information, make corrections if needed, and electronically submit the application and a submission confirmation will be presented. Applicants will be able to print copies for their records.

WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than \$250,000, or both.

Select Your Business Category

Form 224

[Practitioner \(MD, DO, DDS, DMD, DVM, DPM\)](#)
[Mid Level Practitioner \(NP, PA, OD, etc.\)](#)
[Pharmacy](#)
[Hospital/Clinic](#)
[Teaching Institution](#)

[Automated Dispensing Machines \(Login\)](#)

Active Military Only

[Military Form 224](#)

[Civil Service Practitioner/MLP
Assigned to Military Installations
Form 224](#)

[Federal Practitioner/MLP Assigned to
Federal Installations \(Not Military or Contractor\)
Form 224](#)

Form 225

[Manufacturer](#)
[Importer](#)
[Exporter](#)
[Distributor](#)
[Reverse Distributor](#)
[Researcher](#)
[Canine Handler](#)
[Analytical Lab](#)

Form 363

[Narcotic Treatment Clinics](#)

Form 510

[Chemical Manufacturer](#)
[Chemical Importer](#)
[Chemical Exporter](#)
[Chemical Distributor](#)

Select One Business Activity

Applying for a registration with the wrong Business Category/Activity will cause either delay in processing your application or the withdrawal of your application. If you are not certain of your Business Category/Activity, please contact DEA Customer Service at 1-800-882-9539.

- Select Activity -

Continue

Cancel



Referred to as Drug Codes, or the Administration Controlled Substances Code Number

- **21 CFR § 1301.13(f)** - Each application for registration to handle any basic class of controlled substance listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each basic class to be covered by such registration.
- **21 CFR § 1301.13(g)** - Each application for registration to import or export controlled substances shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each controlled substance whose importation or exportation is to be authorized by such registration. Registration as an importer or exporter shall not entitle a registrant to import or export any controlled substance not specified in such registration.
- **21 CFR § 1301.13(h)** - Each application for registration to conduct research with any basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each such basic class to be manufactured or imported as a coincident activity of that registration.
- **21 CFR § 1309.32(d)** - Each application for registration must include the Administration Chemical Code Number, as set forth in § 1310.02 of this chapter, for each List I chemical to be manufactured, distributed, imported, or exported.





- **Schedule I**
 - **All Schedule I applications** must list the Drug Code the applicant will be handling.
- **Schedule II**
 - **All Schedule II Manufacturer** applications must list the Drug Code the applicant will be handling.
 - **Researchers manufacturing or importing a Schedule II as a coincident activity** of that registration.
- **All Import or Export applications** must list the Drug Code the applicant will be handling.
- **All Chemical Manufacturers, Distributors, Importers, and Exporters** must list the List I Drug Code the applicant will be handling.



Registration Fee Schedule



DEA is authorized by **21 U.S.C. 821** to collect “reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions.”

Registrant Type	Registration Period	Fees as of 10/1/2020
Retail Registrants	3 Years	\$888
Manufacturer CS/Chemical	1 Year	\$3,699
Distributor CS/Chemical	1 Year	\$1,850
Reverse Distributor	1 Year	\$1,850
Researcher	1 Year	\$296
Analytical Lab	1 Year	\$296
Importer CS/Chemical	1 Year	\$1,850
Exporter CS/Chemical	1 Year	\$1,850
NTP	1 Year	\$296



Application Control Numbers



Assigned applications that are **received and pending approval**

- 1st character of control numbers are:
 - “W” represents applications submitted electronically (web)
 - Paper applications no longer available as of May 11, 2022
- 2nd and 3rd characters represent calendar year (22 for 2022)
- Last character represents business activity of applicant:

A = Retail Pharmacy	B = Hospital	C = Physicians
E = Manufacturer	F = Distributor	G = Researcher
H = Analytical Lab	J = Importer	K = Exporter
L = Reverse Distributor	N,P,R,S,T,U = Narcotic Treatment Programs	
M = Mid-Level Practitioner		
W = Chemical Manufacturer		
Y = Chemical Distributor		
X = Chemical Importer		
Z = Chemical Exporter		

Completed Internet Form - NOT FOR SUBMISSION
DEA/Control Number - W22011390M ←
Submission Date: Tue Feb 01 12:54:30 EST 2022





21 C.F.R. Section 1301.15 Additional information.

- The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.



Withdrawal of Application

(21 C.F.R. Section 1301.16)



21 C.F.R. Section 1301.16 Amendments to and withdrawal of applications.

- **(a)** An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1301.37. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.
- **(b)** After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.



Refunds

(21 C.F.R. Section 1301.13(e))



As of July 24, 2020, **21 CFR Section 1301.13(e)** and **21 CFR 1309.12(b)** allow for refunds that meet very strict requirements. The regulations were further clarified in the Federal Register (85 FR 14810, 2020-05159). Refunds outside the circumstances will not be authorized.

As a summary:

These provisions of the rule will give the DEA Administrator discretionary authority to refund registration fees in limited circumstances:

- Applicant error
 - Duplicate payment for the same renewal
 - Incorrect billing or incorrect transposing of credit card digits
 - Payment for incorrect business activity
 - Applicant is fee-exempt
- DEA Error
- Death of a registrant within the first year of the three-year registration cycle





Controlled Substances Registration Numbers:

- DEA numbers = nine (9) characters

1st character = letter that indicates registrant category

- A/B/F/G/M/P/R

2nd character

- first letter of registrant's last name (individual)
- first letter of business name (business)
- if the business name begins with a number, the number "9" is used





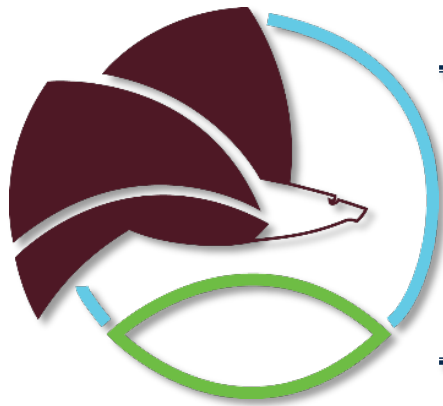
DEA chemical registration numbers:

- DEA numbers = nine (9) characters
- First six characters = numbers
- Seventh character = first letter in registrant's name
- Eighth character = random letter
- Ninth character = letter that identifies business activity of registrant.

W.....Manufacturer (for distribution)	Y.....Distributor
X.....Importer	Z.....Exporter

Example: 012345XAZ





Common Questions





Controlled Substance Ordering System:

CSOS allows for secure electronic controlled substances orders without the supporting paper DEA Form 222.

21 C.F.R. § 1311.40 – Renewal of certificates

- A CSOS certificate holder must generate a new key pair and obtain a new CSOS digital certificate when the registrant's DEA registration expires or whenever the information on which the certificate is based changes.

21 C.F.R. § 1311.30 - Requirements for Storage and Usage

- The certificate holder must report the loss, theft, or compromise of the private key or the password, via a revocation request, to the Certification Authority within 24 hours of substantiation of the loss, theft, or compromise.



Controlled Substance Ordering System (CSOS)



The screenshot shows the DEA E-Commerce Program website. At the top, it reads "Drug Enforcement Administration | Diversion Control Division" and "E-Commerce Program". The main heading is "Controlled Substance Ordering System". Below this, there are three tabs: "For Purchasers", "For Suppliers", and "For Developers". The main content area explains that the CSOS allows for secure electronic transmission of Schedule I-V controlled substance orders without the supporting paper Form 222. A list of links includes: "Enroll in CSOS", "Learn about CSOS", "Request your enrollment status", "Activate/Retrieve your certificate(s)", "Transfer certificate(s) to another computer", "Learn about electronic ordering", "Renew certificate(s)", "Revoke certificate(s)", and "Report a security concern". A callout box titled "Just getting started?" states that Schedule II controlled substances can now be ordered electronically without a paper form DEA-222, and that individuals must enroll in the CSOS Program, with a link to "Click here to enroll today." The left sidebar contains "Site Navigation" (Home, About CSOS, Policies, Enroll in CSOS, Certificate Management, CSOS Reporting, Developer Resources, Contact Support), "Quick Links" (a dropdown menu), and "External Links" (logos for the Department of Justice, DEA, and the Diversion Control Division, along with the FIRSTGOV.gov logo).

Support staff members are available Monday through Friday, from 8:30 AM through 5:50 PM (EST).

1-877-DEA-ECOM (1-877-332-3266)

www.deaecom.gov

When can I Renew?



- An electronic notification is sent to a registrant 60 days from expiration date and then additional renewal notifications are sent 45 days, 30 days, 15 days, and then lastly, at 5 days from expiration.
- If renewal application is not submitted by the expiration date, the registration status is changed from Active to Expired.
- If renewal application is not received within 30 days of the expiration, the expired DEA number will be retired.
- All renewals can be completed online at: www.DEAdiversion.usdoj.gov

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

HOME REGISTRATION REPORTING RESOURCES ABOUT US

Registration Support
Call: 1-800-882-9539 (8:30 am-5:50 pm ET)
Email: DEA.Registration.Help@dea.gov
Contact Local Registration Specialist

Renewal Applications
New Applications
Check the Status of My Application
Registrant Validation Toolset
Request Copy of DEA Certificate
Request Copy of Last Application/Receipt
Make Changes to My DEA Registration
Order Form Request (DEA Form 222)
Registration for Disposal of Controlled Substances
Search for Year Round Pharmaceutical Disposal Locations

Need to Obtain or Renew Your DEA Registration?
Save Time, Apply Online

Please note: The Registrant's email accuracy is important



How can I modify my DEA registration?

(21 C.F.R. Section 1301.51(a))



- Any registrant may apply to modify his/her registration to authorize the handling of additional substances or to change his/her name or address by submitting a letter of request to the Registration Unit, DEA.
- Online changes for name, address, and drug codes, may also be done via the Diversion website and require an electronic signature by the registrant.

A green rounded rectangle containing a list of services. An orange arrow points to the option "Make Changes to My DEA Registration".

Registration Support
Call: 1-800-882-9539 (8:30 am-5:50 pm ET)
Email: DEA.Registration.Help@dea.gov
Contact Local Registration Specialist

- Renewal Applications
- New Applications
- Check the Status of My Application
- Registrant Validation Toolset
- Request Copy of DEA Certificate
- Request Copy of Last Application/Receipt
- Make Changes to My DEA Registration** ←
- Order Form Request (DEA Form 222)
- Registration for Disposal of Controlled Substances
- Search for Year Round Pharmaceutical Disposal Locations

A screenshot of the DEA Diversion Control Division website. The page header includes the U.S. Department of Justice and Drug Enforcement Administration logos, and the text "U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION" and "DIVERSION CONTROL DIVISION". Below the header is a "Registration Tools" link. The main content area is titled "CSA Registration Update: Login Information" and contains instructions for logging in. It includes a text input field for the DEA Number, Control Number, or Web Tracking Number, and "Next" and "Clear" buttons. At the bottom, there is a "Having Trouble Logging In?" section with contact information for email and toll-free phone support.

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION

[Registration Tools](#)

CSA Registration Update: Login Information
You will need information from your **registration certificate** in order to login.

For Active Registrants, enter your DEA Number (Not Case Sensitive).
For New Applicants, enter the Web Tracking Number or Control Number
from your confirmation page or receipt.



How can I Terminate My Registration?

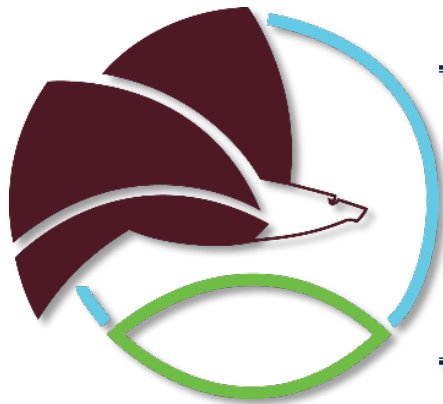
(21 C.F.R. Section 1301.52)



A registration such shall terminate without any action by the Administration, if and when a registrant:

- Dies
- Ceases legal existence
- Discontinues business or professional practice
- Voluntarily retires registration – via written correspondence





Common Problems Encountered

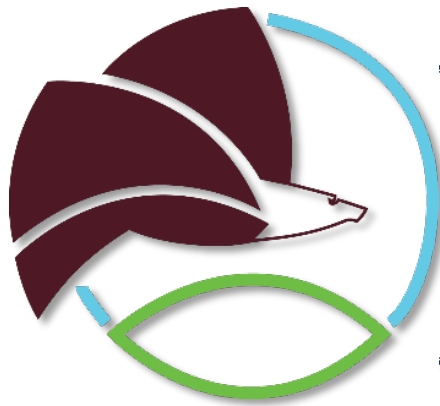


Common Problems Encountered



- The applicant does not have appropriate state authority.
- The applicant assumes their first registration period will be a full 12 months once approved.
- Failure to notify DEA of an email change.
- Failure to notify DEA of an address change.
- Failure to update state licensure expiration dates.





Assistance with Registration Matters



Registration Resources

Diversion Control Division Website www.DEAdiversion.usdoj.gov

- Registration Support
- Get Email Updates
- What's New
- Questions & Answers
- Quick Links
- Additional Resources
- Contacts (About Us)

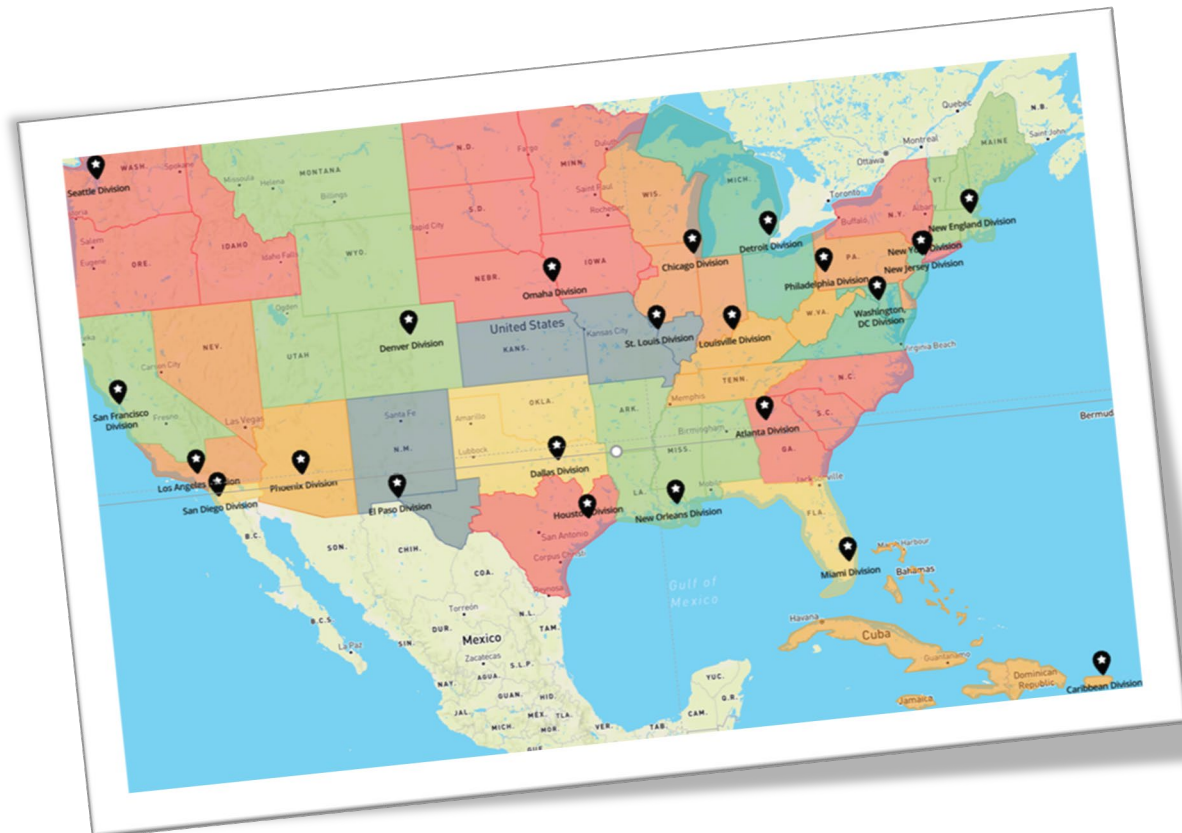
The screenshot shows the homepage of the Diversion Control Division website. At the top, it features the DEA logo and the text "U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION" and "DIVERSION CONTROL DIVISION". A search bar is located on the right. Below the header, a red banner reads "Attention: Requirements for training for Medication Assisted Treatment as part of the MATE Act (March 27, 2023)". A navigation menu includes "HOME", "REGISTRATION", "REPORTING", "RESOURCES", and "ABOUT US". The main content area is divided into several sections: "Registration Support" with contact information and links for renewal and new applications; a social media section for Twitter with the handle @DEAHQ and the hashtag #DEADIVERSION; "In The News" with a "Get Email Updates" button and several news items; "What's New" with links to proposed amendments and other updates; "EMERGENCY DISASTER RELIEF"; "Search for Year Round Pharmaceutical Disposal Locations"; "DEA NATIONAL TAKEBACK" (National Prescription Drug Take Back Day); and "Report Illicit Pharmaceutical Activities" (RX ABUSE ONLINE). A footer section contains "HOME", "CONTACT US", "A-Z SUBJECT INDEX", "PRIVACY NOTICE", and "WEBSITE ASSISTANCE". Below this, there are three columns of links: "REGISTRATION" (Applications, Tools, Resources, etc.), "REPORTING" (ARCOS, BCM Online, etc.), and "RESOURCES" (Chemical Control Program, OMEA, etc.). The "DIVERSION CONTROL DIVISION" logo is in the bottom right corner.

Assistance with Registration Matters



The Registration Program Specialists are stationed around the country, providing front line registration activities by:

- Serving as DEA's liaison with the medical community, the public, potential and current registrants, and numerous governmental personnel.
- Independently managing the registration program for the field division.
- Examining all registration transactions and rejects those not in compliance with agency standards and other applicable laws, rules, and regulations.
- Conducting presentations and training sessions on DEA's Registration Program and process to the registrant community.



Assistance with Registration Matters



If you need any assistance with a registration matter, please use one of the following:



You can find your local RPS by visiting www.DEAdiversion.usdoj.gov and select **Contact Local Registration Specialist.**



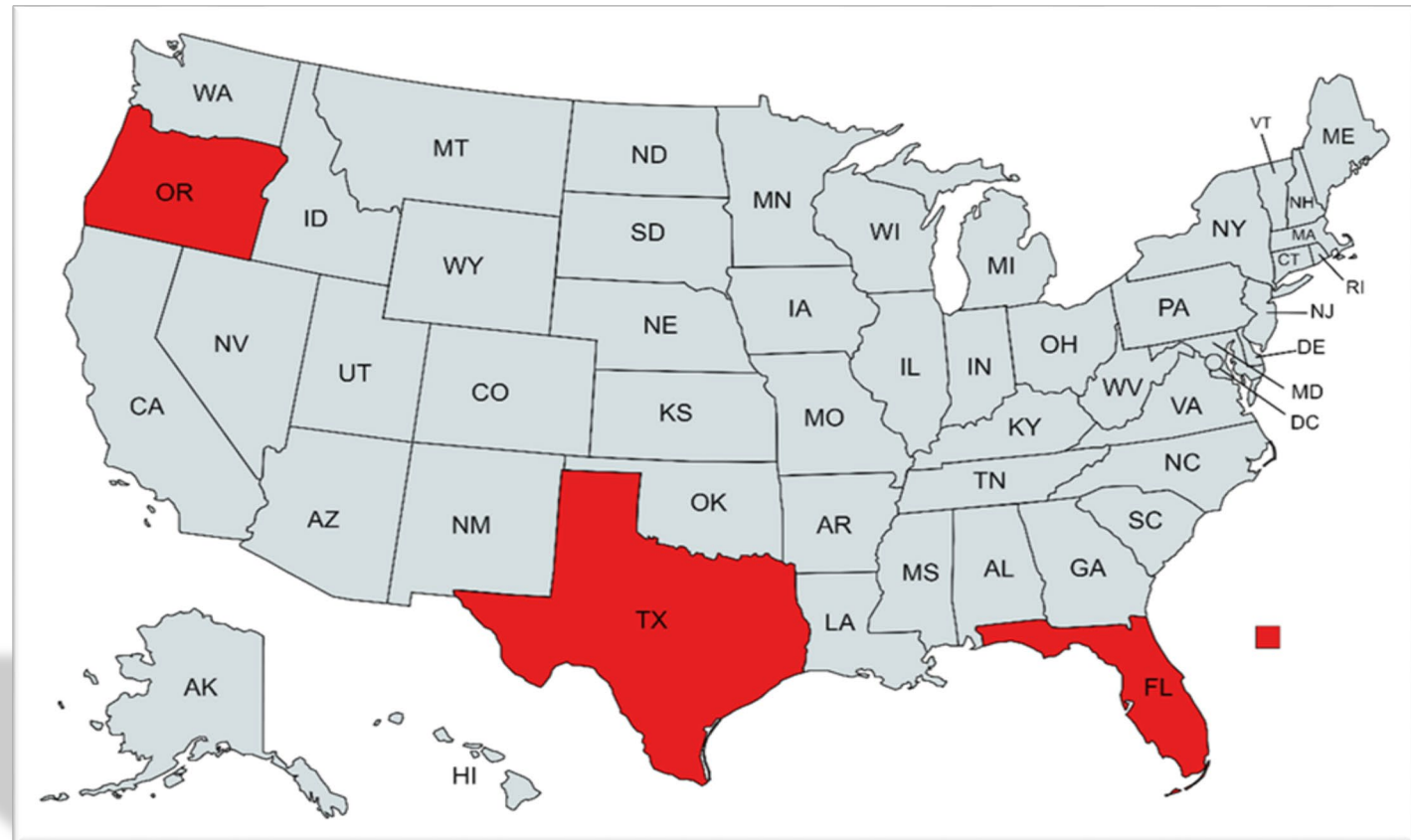
Assistance with Registration Matters



Registration Call Centers handle calls and emails from those seeking registration and CSOS assistance.

Currently we have three Call Center hubs located in:

- Weston, Florida
- El Paso, Texas
- Medford, Oregon





DEA Headquarters

Diversion Control Division

Registration and Program Support Section (DRR)

Registration Call Center

- **1-800-882-9539**
- **Email Us: DEA.Registration.Help@dea.gov**





Thank You!

Holly Farrington

Program Analyst | Diversion Registration and Program Support Section (DRR)

United States Drug Enforcement Administration

Washington D.C.

Ofc. 571.324.7471

Holly.M.Farrington@DEA.gov

