DRUG ENFORCEMENT ADMINISTRATION

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

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- 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.

Registration and Program Support Section (DRR)

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

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 posses, 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

Applications

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):

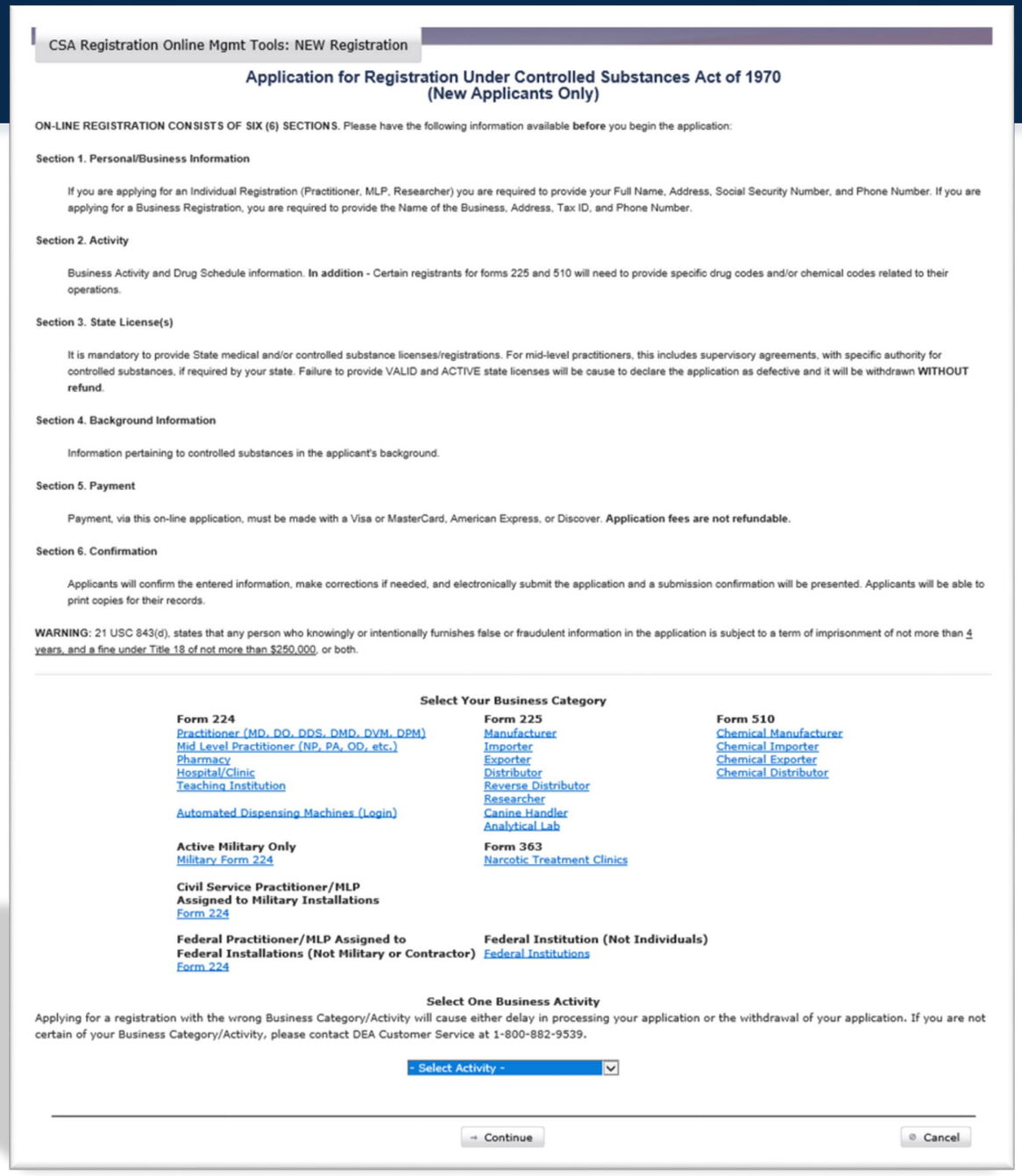
510 New & 510A Renewal

- 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

New Applications



Drug Codes on Applications/Registrations

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.

Drug Codes on Applications/Registrations

- **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

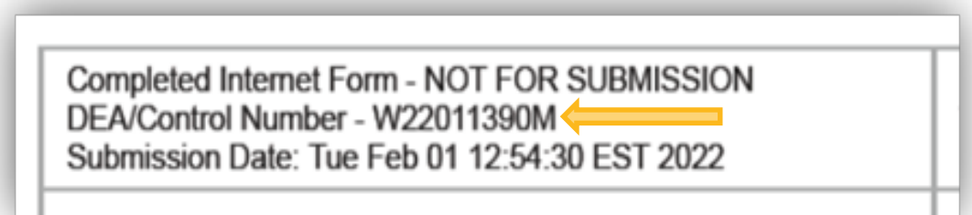
Assigned applications that are **received and pending approval**

- 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



Additional Information
(21 C.F.R. Section 1301.15)

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

DEA Registrations

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 Registrations

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)

Controlled Substance Ordering System:

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

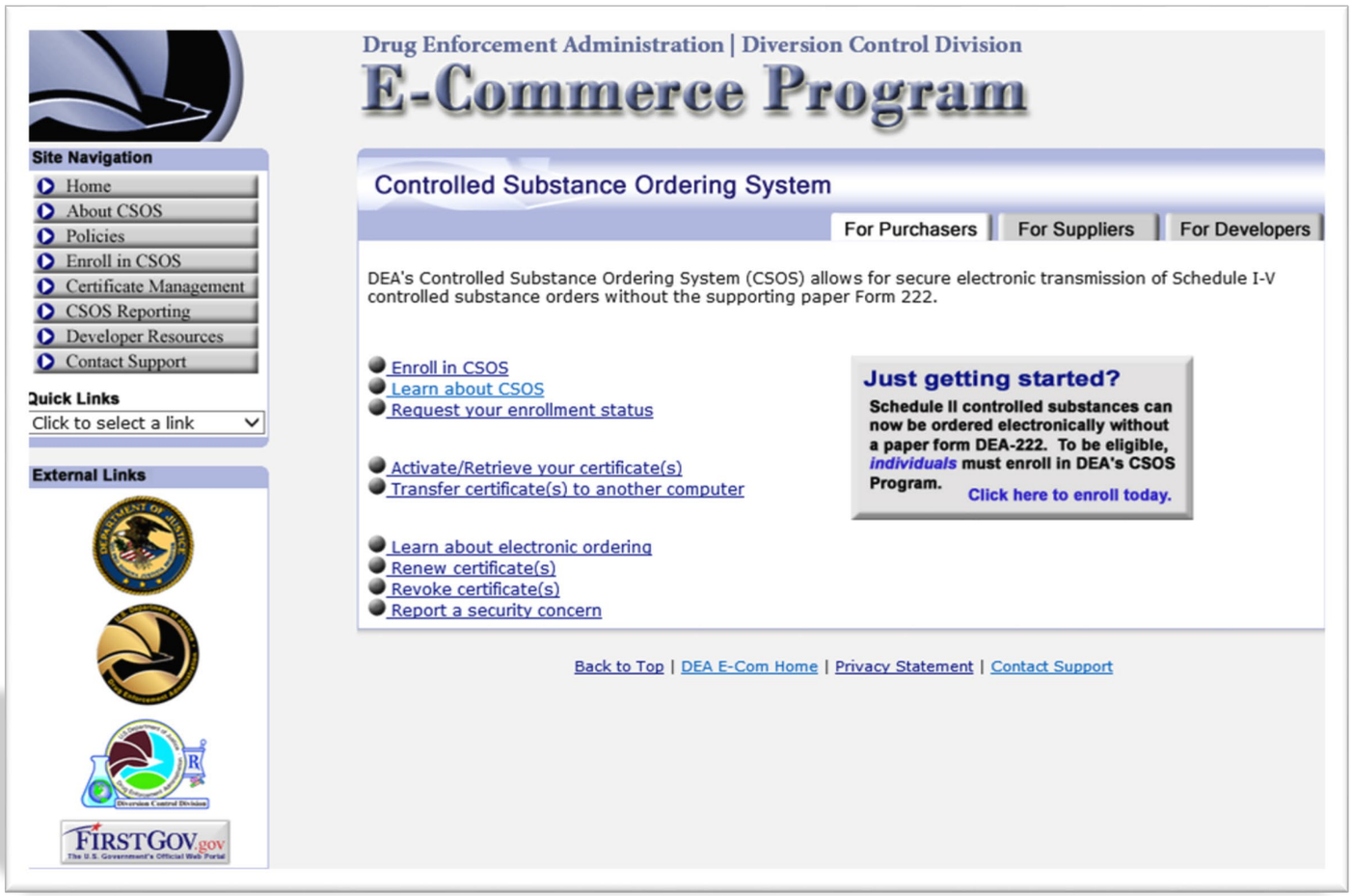
21 C.F.R. § 1311.40 – Renewal of certificates

- 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)



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

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.

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

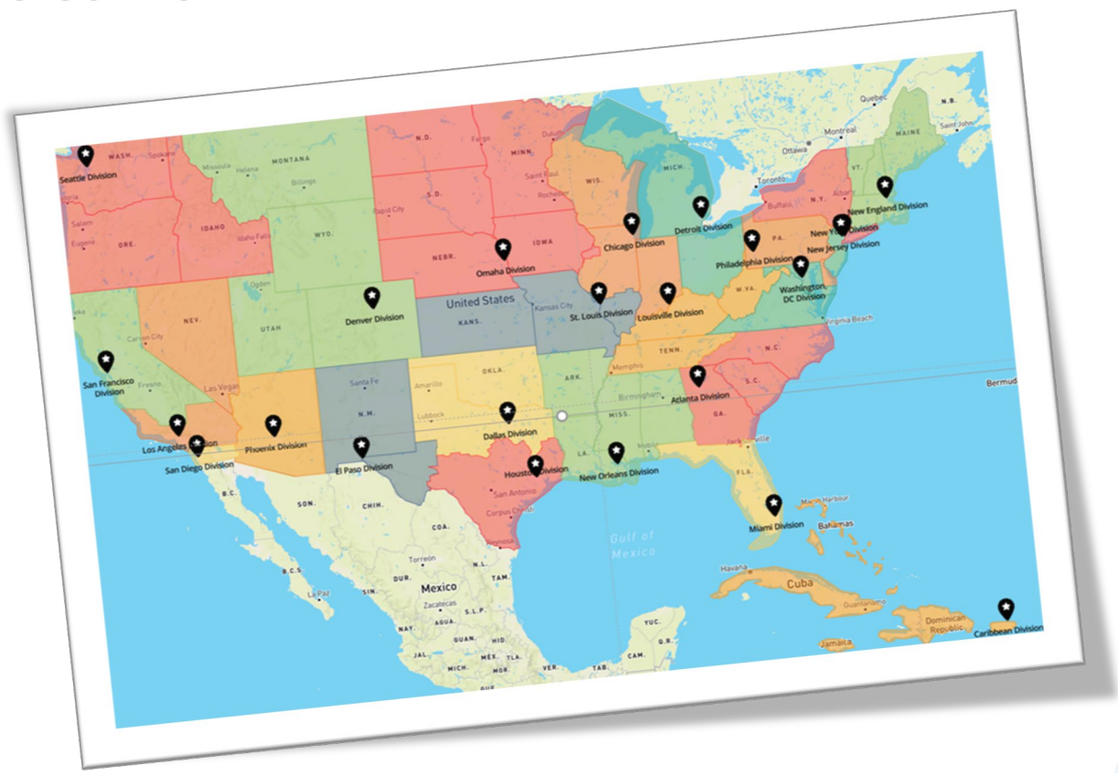
www.DEAdiversion.usdoj.gov

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

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:

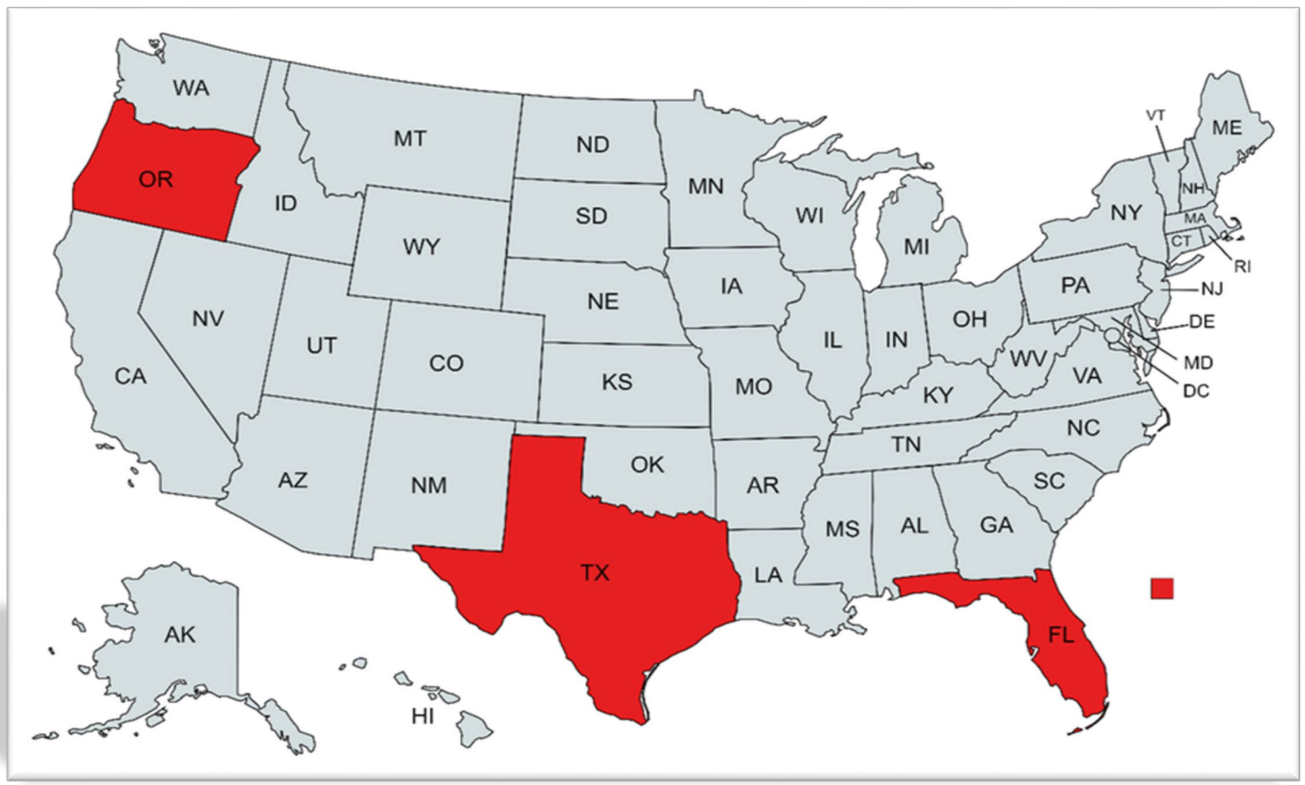
You can find your local RPS by visiting www.DEAdiversion.usdoj.gov and select **Contact Local Registration Specialist.**

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



Assistance with Registration Matters

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!

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