Disclaimer



The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way.

This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

I have no financial relationship to disclose.

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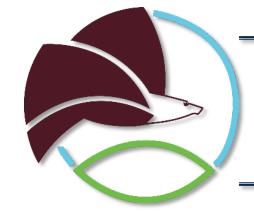


Registration Program Overview & Updates

Michelle McGregor Acting Unit Chief

Supply Chain Conference





Topics that will be Covered

Topics that will be Covered



Registration and Business Operations Section (DRR)

Registration Updates

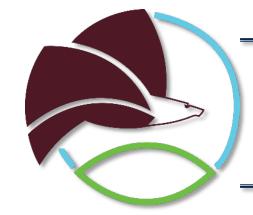
Common Problems Encountered

Common Questions

Assistance with Registration Matters

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Who is the

Registration and Business Operations Section

Registration and Business Operations 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 95 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 Business Operations Section (DRR)



Units within DRR

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

Registration and Business Operations Section (DRR)



Total Registrant Population: 2,176,958

BUSINESS ACTIVITY	REGISTRANTS
PHARMACY	67939
HOSPITAL/CLINIC	20278
PHYSICIANS	1450204
TEACHING INSTITUTION	247
MANUFACTURING	566
DISTRIBUTOR	643
RESEARCHER (II-IV)	8665
DOG HANDLERS	3009
RESEARCHER (I)	854
ANALYTICAL LAB	1517
MPORTER (277
EXPORTER	277
REVERSE DISTRIBUTOR	73
MID LEVEL PRACTITIONER (MLP)	619285
NARCOTIC TREATMENT PROGRAM (NTP)	
MAINTENANCE	283
DETOXIFICATION	86
MAINTENANCE/DETOXIFICATION	1789
COMPOUNDER/MAINTENANCE	6
COMPOUNDER/MAINTENANCE/DETOXIFICATION	67
CHEMICAL	
MANUFACTURING	220
IMPORTER	231
DISTRIBUTOR	289
EXPORTER	153
GRAND TOTALE	2176958

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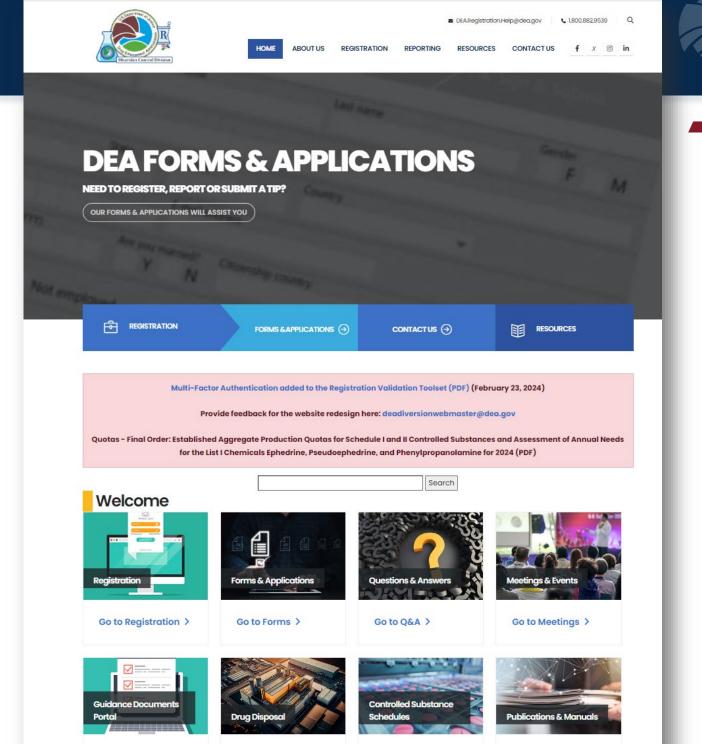


Registration Updates

DEA Diversion website

www.DEAdiversion.usdoj.gov

- Top Tabs
- Quick Buttons (blue)
- Welcome Buttons
- •Scroll down for:
- •In the News
- What's New
- •Email updates



Go to Schedules >

Go to Pubs >

Go to Portal >

Go to Disposal >

DEA Diversion website



DEA Forms & Applications



Registration Applications Check the status of my application

Request Copy of Application/ Receipt Request Copy of DEA Certificate

Make Changes to My DEA Registration

Registration for disposal

Registration Validation Toolset Order Form Request (DEA Form 222)

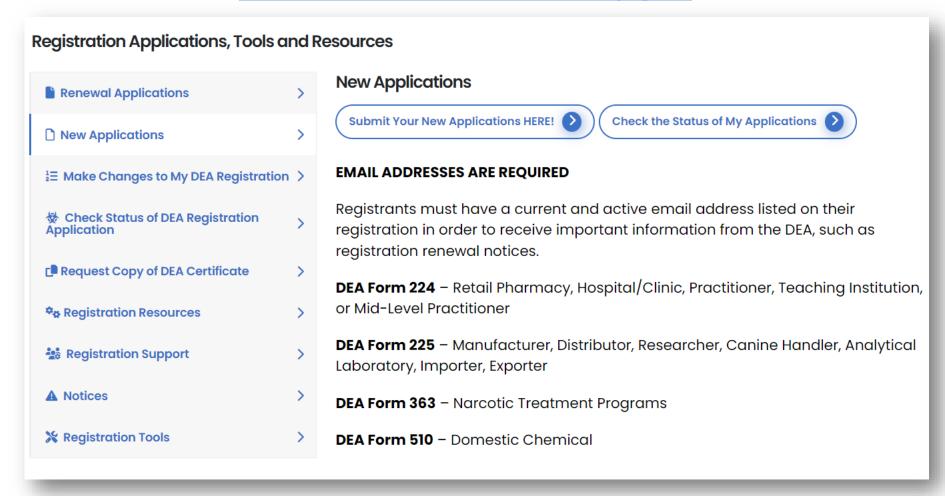
CSOS

DEA Applications



Applications must be submitted online via the DEA Diversion website:

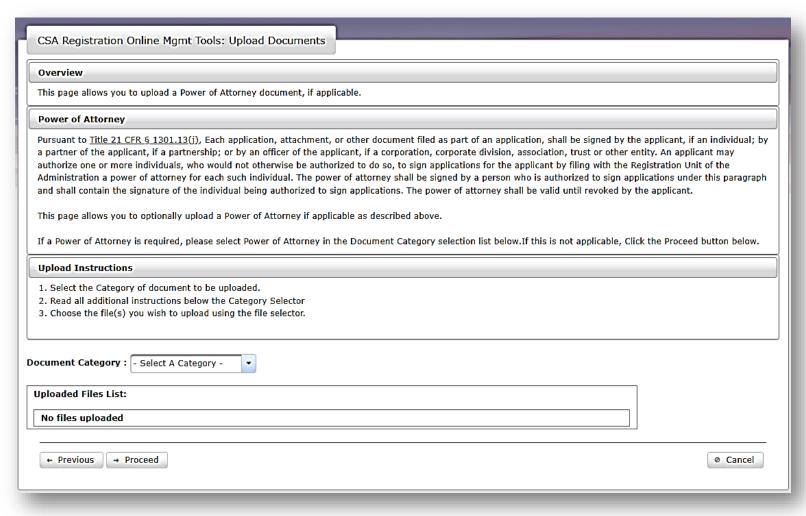
www.DEAdiversion.usdoj.gov



DEA Applications - Power of Attorney



A Power of Attorney can be uploaded on DEA Registration applications & modification forms. Refer to **21 CFR § 1301.13(j)** for more information.



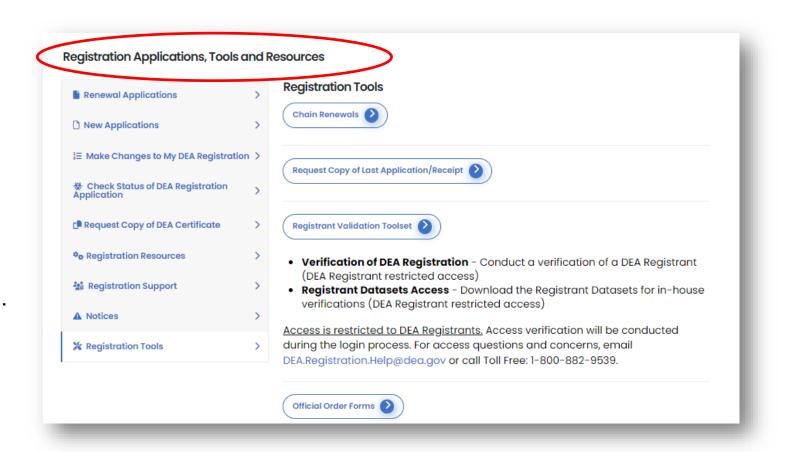
DEA Certificates and Receipts



We now e-mail application submission receipts and DEA Certificates.

If necessary, you can obtain a copy from our website.

The Registration Call Center can also assist by sending these items to the email on file.



Please note: the submission receipt is a not financial receipt.





Security Enhancements



New security features require you to keep the email address and contact number associated with your registration up to date.

- If the email address is altered or updated, the formatting will be automatically verified for validity.
- These updated security measures will help assure only those with proper credentials can access your registrant information.



Security PIN Validation:

This security feature is used to confirm the identity of a caller or emailer.

 We will text the 6-digit security PIN to the cell phone number on file and have the Registrant or Power of Attorney holder recite the PIN back to continue the call.

 If there is no cell phone number on file, a second method is to send the security PIN to the email on file and have it recited back.



Multi-Factor Authentication:

This security feature is necessary for DEA to continue to keep our Registrants' Personally Identifiable Information safe and secure.

- DEA is aware that the implementation of this security measure may present some challenges to the business operations of our Registrant community.
- This security enhancement requires verification of the Registrant's identity through multi-factor authentication when accessing your registration on our website, which also includes accessing the Registrant Validation Toolset.



Multi-Factor Authentication – Validation Token:





Validation Token Email:

DEA Registration Account Login: Validation Token

From: <u>DEA.Registration.Help@dea.gov</u>

to me

Dear Applicant,

Your validation token [Generated at May 12, 2023 03:19:31 PM EDT] for login to your DEA CSA Registration account is

3AV5JF3D

This token will expire at May 12, 2023 03:20:31 PM EDT, so please enter it on the validation page as soon as possible. If you did not request this token, please contact:

Call us toll free: 1-800-882-9539 or Email us: DEA.Registration.Help@dea.gov



If you find yourself locked out of our online applications and tools, you may wait until the temporary lock is removed or contact the Registration Helpdesk.





Registration Validation Toolset on www.DEAdiversion.usdoj.gov

- Verification of DEA Registration Conduct a verification of a DEA Registrant (DEA Registrant restricted access)
- Registrant Datasets Access Download the Registrant
 Datasets for in-house verifications (DEA Registrant restricted access)

Access verification will be conducted during the login process (MFA Token). For access questions and concerns, email DEA.Registration.Help@dea.gov or call: 1-800-882-9539.



Registrant Datasets Access (RDA)



Access to the DEA Controlled Substances Act Registration Information Database, and the dataset contained within, is limited to those registered with, or by request to, the Drug Enforcement Administration in order to comply with Federal, State, and local, Statutes and Rules.

This includes those that provide credentialing or verification services to the Pharmaceutical and Healthcare industry.

Please note:

- Access must be applied for annually
- RDA access requires a login & password
- To obtain an application or submit the completed form and any supporting documentation e-mail DEA.CSARDA@dea.gov

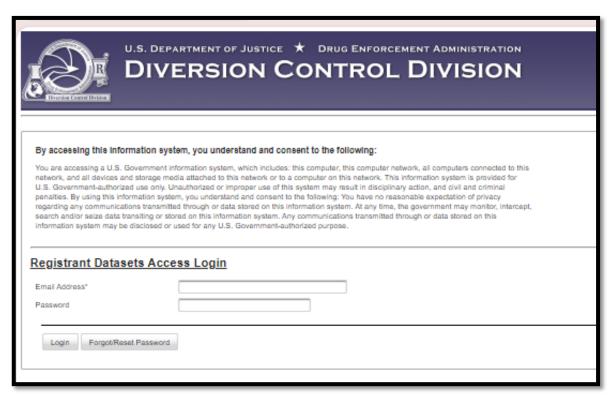
Be advised that the unauthorized distribution, reverse engineering, re-engineering, profit from the sale, the incorporation in a software system or package for distribution, or the use for marketing and/or targeting, are strictly forbidden and not allowed uses of the dataset from the Controlled Substances Act Registration Information Database.

Registrant Datasets Access (RDA)



Full access users can conduct a primary source registration verification of a DEA registrant, and/or download the dataset files that can then be used in a <u>self-designed</u> system. The information provided is updated nightly and is provided at no cost.

- If approved, an email will be sent to your email with your temporary password. Note: your email will be the Login.
- The RDA is not accessible through our website.
- You can have each team member request their own account.



Please note: there is a option to reset password on the login page

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Common Problems Encountered

Common Problems Encountered



- The applicant does not have appropriate state authority, prior to applying.
- The applicant assumes their first registration period will be a full 12 or 36 months.
- Failure to notify DEA of an email change.
- Failure to notify DEA of an address change.
- Failure to update state licensure expiration dates.
- Failure to upload a POA.

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Common Questions

Renewals



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.

- For bulk manufacturers and importers of schedules 1 & 2, a letter is sent 120 days prior to expiration date.
- If a renewal application is **not** submitted by the expiration date, the registration status changes from Active to Expired.
- If a renewal application **is not received** within 30 days of the expiration date, the expired DEA number will be retired.

Renewals can be completed online at: www.DEAdiversion.usdoj.gov

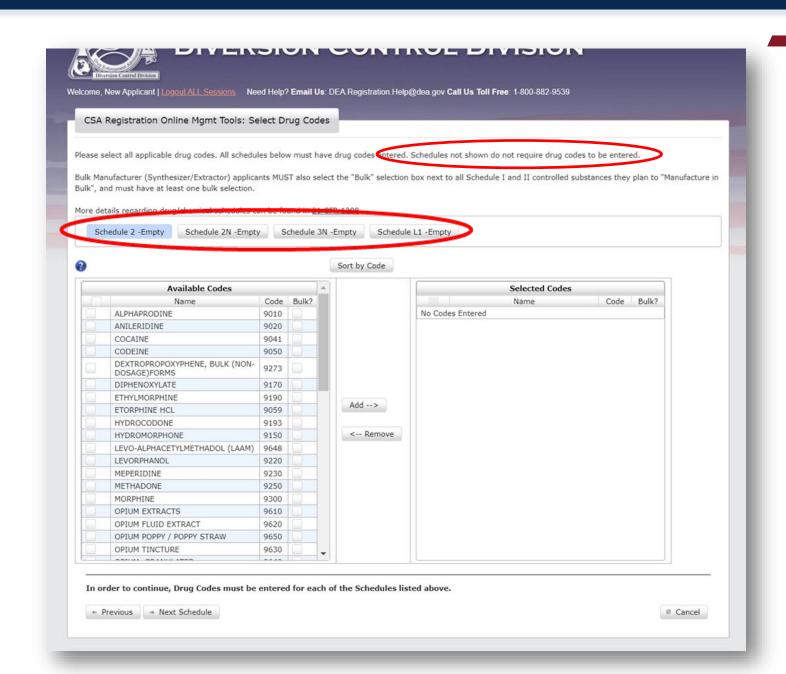
Please note: email accuracy is important.

DEA Applications & Drug Codes



When completing an application with drug codes:

- The application will indicate when drug codes are needed.
- In order to continue with the application, Drug Codes must be entered for each required schedule.



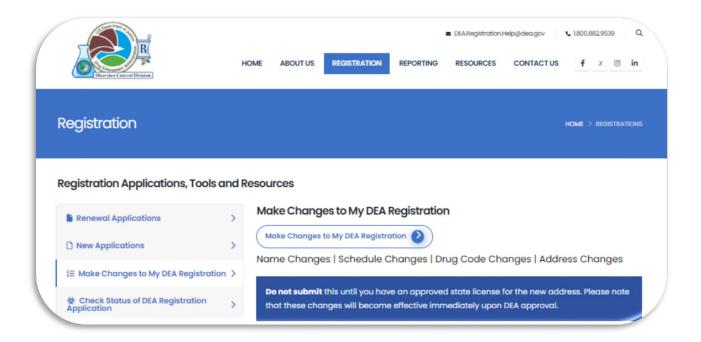
When can I modify my DEA registration?



21 CFR § 1301.51(a) - Modification in Registration

"Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address by submitting a written request to the Registration Unit, Drug Enforcement Administration...

Additionally, such a request may be submitted on-line at www.DEAdiversion.usdoj.gov."



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 CFR § 1311.30(e) - 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"...

21 CFR § 1311.40(a) - Renewal of certificates

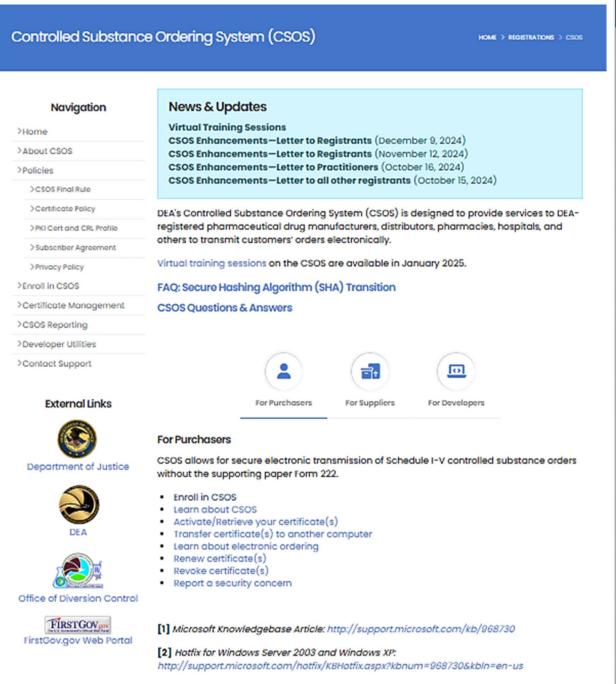
"A CSOS certificate holder must generate a new key pair and obtain a new CSOS digital certificate when the registrant's DEA registration expires or whenever the information on which the certificate is based changes"...

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



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Assistance with Registration Matters

Assistance with Registration Matters



The Registration Program Specialists (RPS) are stationed around the country and serve as DEA's liaison with the medical community, the public, potential and current registrants, and numerous governmental personnel.

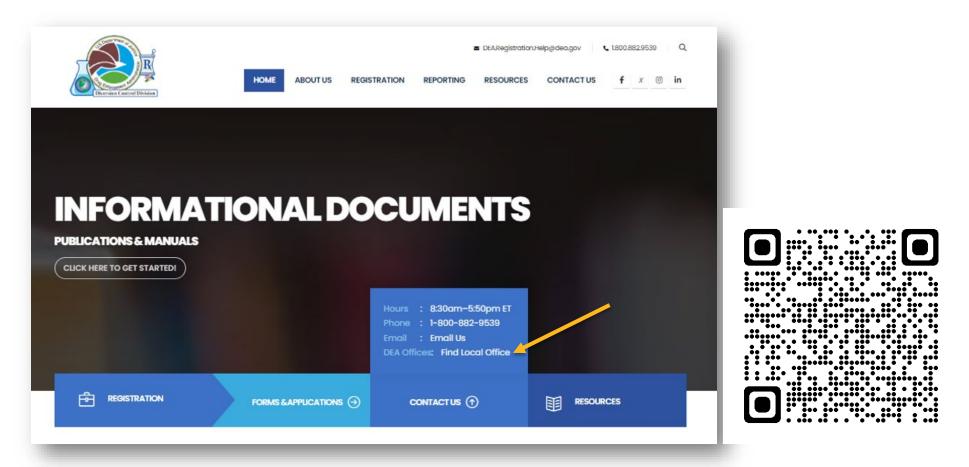
- Independently manage the registration program, for the field division.
- Examine registration transactions and rejects those not in compliance with agency standards and other applicable laws, rules, and regulations.
- Conduct presentations and training sessions on DEA's Registration Program and process 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 Registration Specialist by visiting www.DEAdiversion.usdoj.gov
Contact us – Find Local Office

Assistance with Registration Matters



DEA Headquarters
Diversion Control Division
Registration and Business Operations Section (DRR)

The Registration Call Center handles calls and emails from those seeking Registration and CSOS assistance:

1-800-882-9539

Email Us: DEA.Registration.Help@dea.gov

Contact us

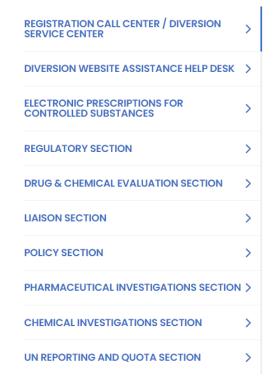




Contact Diversion Control Division

The mission of DEA's Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

Program Contacts



REGISTRATION CALL CENTER / DIVERSION SERVICE CENTER

ARCOS Reporting, CSA, Registration Applications, Changes to Name, Address, and/or Schedules, Fee Exempt, CMEA, Data-Waived Physicians, Mid-Level Practitioners

1-800-882-9539 or DEA.Registration.Help@dea.gov

To better serve your needs, please include the following information:

Subject Line:

Brief Description Title (i.e., Address Changes, CMEA, Renewal Applications, New Applications, etc.)

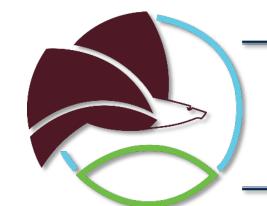
Body:

Describe the reason for your email. Include your contact information.



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Thank You!

Michelle McGregor, Acting Unit Chief
Registration Support and Business Operations Section (DRR)
Contact information: Michelle.S.McGregor@DEA.gov or 571-324-8635