

Supply Chain Conference 2025 Registration and Business Operations Section (DRR)







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I have no financial relationship to disclose.





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Registration Program Overview & Updates

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Supply Chain Conference







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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- 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 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 I	REGISTRANTS
PHARMACY	67939
HOSPITAL/CLINIC (20278
PHYSICIANS	1450204
TEACHING INSTITUTION	247
MANUFACTURING	566
DISTRIBUTOR (643
RESEARCHER (II-IV)	8665
DOG HANDLERS I	3009
RESEARCHER (I)	854
ANALYTICAL LAB	1517
IMPORTER I	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 I	231
DISTRIBUTOR	289
EXPORTER (153
GRAND TOTAL:	2176958

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DEA Diversion website



HOME

ABOUT US REGISTRATION

REPORTING

RESOURCES

■ DEARegistration.Help@dea.gov 🕻 1.800.882.9539 🔍

CONTACTUS

f X O in

www.DEAdiversion.usdoj.gov

Top TabsQuick Buttons (blue)Welcome Buttons

•Scroll down for:

In the News

What's New

•Email updates



DEA Diversion website

DEA Forms & Applications

Registration Applications Check the status of my application

RequestRequestCopy ofCopy ofpplication/DEAReceiptCertificate

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

Registration Applications, Tools a	nd R	esources
Renewal Applications	>	New Applications
New Applications	>	Submit Your New Applications HERE! OCheck the Status of My Applications
¹ Ξ Make Changes to My DEA Registration	>	EMAIL ADDRESSES ARE REQUIRED
袋 Check Status of DEA Registration Application	>	Registrants must have a current and active email address listed on their registration in order to receive important information from the DEA, such as registration renewal notices.
Prequest Copy of DEA Certificate	>	DEA Form 224 – Retail Pharmacy, Hospital/Clinic, Practitioner, Teaching Institution,
* Registration Resources	>	or Mid-Level Practitioner
🐮 Registration Support	>	DEA Form 225 – Manufacturer, Distributor, Researcher, Canine Handler, Analytical Laboratory, Importer, Exporter
A Notices	>	DEA Form 363 – Narcotic Treatment Programs
X Registration Tools	>	DEA Form 510 – Domestic Chemical



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

CSA Registration Online Mgmt Tools: Upload Documents
Overview
This page allows you to upload a Power of Attorney document, if applicable.
Power of Attorney
Pursuant to <u>Title 21 CFR § 1301.13(j</u>), Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.
This page allows you to optionally upload a Power of Attorney if applicable as described above.
If a Power of Attorney is required, please select Power of Attorney in the Document Category selection list below. If this is not applicable, Click the Proceed button below.
Upload Instructions
 Select the Category of document to be uploaded. Read all additional instructions below the Category Selector Choose the file(s) you wish to upload using the file selector.
Document Category : - Select A Category -
Uploaded Files List:
No files uploaded
← Previous → Proceed

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.

Renewal Applications	> Registration Tools
) New Applications	> Chain Renewals 2
E Make Changes to My DEA Registration	Request Copy of Last Application/Receipt
Check Status of DEA Registration	>
Request Copy of DEA Certificate	> Registrant Validation Toolset
e Registration Resources	• Verification of DEA Registration - Conduct a verification of a DEA Registrant
Registration Support	 (DEA Registrant restricted access) Registrant Datasets Access - Download the Registrant Datasets for in-house
Notices	<pre>verifications (DEA Registrant restricted access) ></pre>
Registration Tools	 <u>Access is restricted to DEA Registrants.</u> Access verification will be conducted during the login process. For access questions and concerns, email
	DEA.Registration.Help@dea.gov or call Toll Free: 1-800-882-9539.

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







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:

U.S. DEPARTMENT OF JUSTICE * DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION Welcome, Logout ALL Sessions Need Help? Email Us: DEA.Registration.Help@dea.gov Call Us Toll Free: 1-800-882-9539
CSA Registration Online Applications: Multi-factor Authentication
As a measure of additional security, please request a code to be sent to your point of contact email address you have provided in your most recent registration application or update, and verify that code below. Send Token

Validation Token Email:

DEA Registration Account Login: Validation Token From: DEA.Registration.Help@dea.gov 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.

CSA Registration Online Applications: Multi-factor Authentication	
For security reasons, your account is currently locked. This lock is temporary. You will be able to log in again at: May 12, 2023 03:23:57 PM EDT	
For Help, please contact us at: Email: DEA.Registration.Help@dea.gov -or- Call Us Toll Free: 1-800-882-9539	
	¢ Refresh

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 <u>DEA.Registration.Help@dea.gov</u> or call: 1-800-882-9539.





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 <u>DEA.CSARDA@dea.gov</u>

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.

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.

	.S. DEPARTMENT OF JUSTICE * DRUG ENFORCEMENT ADMINISTRATION
By accessing this inforr	nation system, you understand and consent to the following:
network, and all devices and U.S. Government-authorized penalties. By using this infor regarding any communicatio search and/or seize data tra	wemment information system, which includes: this computer, this computer network, all computers connected to this storage media attached to this network or to a computer on this network. This information system is provided for use only. Unauthorized or improper use of this system may result in disciplinary action, and civil and criminal mation system, you understand and consent to the following: You have no reasonable expectation of privacy ns transmitted through or data stored on this information system. At any time, the government may monitor, intercept, isiting or stored on this information system. Any communications transmitted through or data stored on this lisclosed or used for any U.S. Government-authorized purpose.
Registrant Datase	ts Access Login
Email Address" Password	
Login Forgot/Rese	Password

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

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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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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: <u>www.DEAdiversion.usdoj.gov</u>

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.

select all applicable drug codes. All schedu			s	
				. Schedules not shown do not require drug codes to be entered.
anufacturer (Synthesizer/Extractor) applica and must have at least one bulk selection.	ints MUS	ST also sele	ect the "Bulk" selection	n box next to all Schedule I and II controlled substances they plan to "Manufacture in
etails regarding devolutionical schedules e			050 1200	
		abadala 28	Cabada	
chedule 2 -Empty Schedule 2N -Empty	y 5	chedule 31	V -Empty Schedu	e L1 -Empty
			[
			Sort by Code	
Available Codes				Selected Codes
Name	Code	Bulk?		Name Code Bulk?
ALPHAPRODINE	9010			No Codes Entered
ANILERIDINE	9020			
COCAINE	9041			
CODEINE	9050			
DEXTROPROPOXYPHENE, BULK (NON- DOSAGE)FORMS	9273			
DIPHENOXYLATE	9170			
ETHYLMORPHINE	9190			
ETORPHINE HCL	9059		Add>	
HYDROCODONE	9193			
HYDROMORPHONE	9150		< Remove	
LEVO-ALPHACETYLMETHADOL (LAAM)	9648			
LEVORPHANOL	9220			
MEPERIDINE	9230			
METHADONE	9250			
	9300			
MORPHINE	9610			
OPIUM EXTRACTS	2010	1.		
OPIUM EXTRACTS OPIUM FLUID EXTRACT	9620	Lui I		
OPIUM EXTRACTS	9620 9650			
OPIUM EXTRACTS OPIUM FLUID EXTRACT	9620			



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 <u>www.DEAdiversion.usdoj.gov</u>."



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

Controlled Substance Ordering System (CSOS) HOME > REGISTRATIONS > CSOS News & Updates Navigation Virtual Training Sessions Home CSOS Enhancements-Letter to Registrants (December 9, 2024) >About CSOS CSOS Enhancements-Letter to Registrants (November 12, 2024) CSOS Enhancements-Letter to Practitioners (October 16, 2024) >Policies CSOS Enhancements-Letter to all other registrants (October 15, 2024) >CSOS Final Rule >Certificate Policy DEA's Controlled Substance Ordering System (CSOS) is designed to provide services to DEAregistered pharmaceutical drug manufacturers, distributors, pharmacies, hospitals, and >PKI Cert and CRL Profile others to transmit customers' orders electronically. Subscriber Agreement Virtual training sessions on the CSOS are available in January 2025. >Privocy Policy >Enroll in CSOS FAQ: Secure Hashing Algorithm (SHA) Transition Certificate Management **CSOS** Questions & Answers CSOS Reporting >Developer Utilities >Contact Support О External Links For Purchasers For Suppliers For Developen For Purchasers CSOS allows for secure electronic transmission of Schedule I-V controlled substance orders Department of Justice without the supporting paper Form 222. Enroll in CSOS Learn about CSOS Activate/Retrieve your certificate(s) Transfer certificate(s) to another computer Learn about electronic ordering Renew certificate(s) Revoke certificate(s) Report a security concern Office of Diversion Control FIRSTGOV [1] Microsoft Knowledgebase Article: http://support.microsoft.com/kb/968730 FirstGov.gov Web Portal [2] Hotfix for Windows Server 2003 and Windows XP: http://support.microsoft.com/hotfix/KBHotfix.aspx?kbnum=968730&kbln=en-us

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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.







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



You can find your local Registration Specialist by visiting <u>www.DEAdiversion.usdoj.gov</u> Contact us – Find Local Office





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





HOME ABOUT US REGISTRATION REPORTING

FESOURCES CONTACT US **f** X I in

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	>	AR
DIVERSION WEBSITE ASSISTANCE HELP DESK	>	an Prc
ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES	>	1-8
REGULATORY SECTION	>	То
DRUG & CHEMICAL EVALUATION SECTION	>	Su Bri
LIAISON SECTION	>	Ар
POLICY SECTION	>	Bo De
PHARMACEUTICAL INVESTIGATIONS SECTION	>	
CHEMICAL INVESTIGATIONS SECTION	>	
UN REPORTING AND QUOTA SECTION	>	

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:

ubject 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: <u>Michelle.S.McGregor@DEA.gov</u> or 571-324-8635