DRUG ENFORCEMENT ADMINISTRATION

Supply Chain Conference 2024

Registration Program Overview & Updates, DRR

April 30 - May 2, 2024

Little Rock, Arkansas

Disclaimer

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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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Topics that will be Covered

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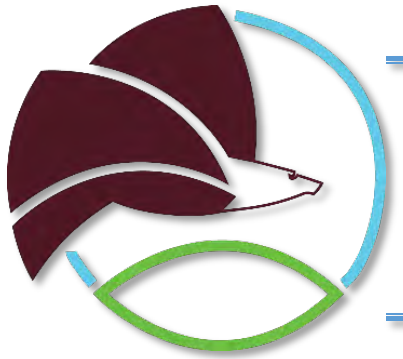
- **Registration and Business Operations Section (DRR)**
- **Registration Updates**
- **Common Problems Encountered**
- **Common Questions**
- **Assistance with Registration Matters**



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 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 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)

Registrant Population: March 2024

BUSINESS ACTIVITY	REGISTRANT POPULATION
PHYSICIANS	1424034
MID LEVEL PRACTITIONER (MLP)	581785
PHARMACY	68911
HOSPITAL/CLINIC	19749
TEACHING INSTITUTION	251
MANUFACTURING	572
DISTRIBUTOR	642
RESEARCHER (II-IV)	8577
DOG HANDLERS	3041
RESEARCHER (I)	847
ANALYTICAL LAB	1535
IMPORTER	268
EXPORTER	268
REVERSE DISTRIBUTOR	76
NARCOTIC TREATMENT PROGRAM (NTP)	2216
CHEMICAL	
MANUFACTURING	213
IMPORTER	221
DISTRIBUTOR	307
EXPORTER	146
	887
GRAND TOTAL:	2113659

Total Registrant Population = 2,113,659

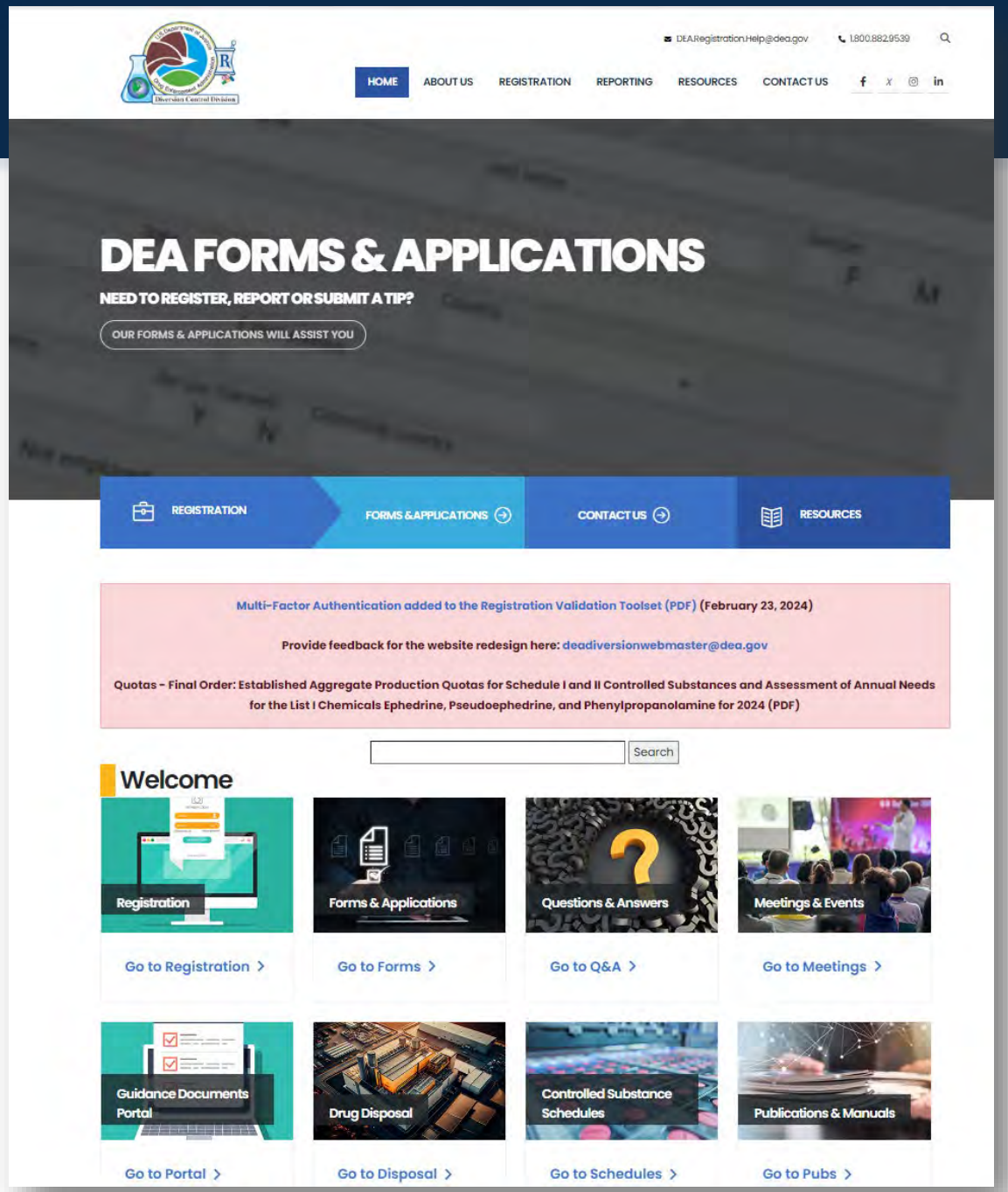
Registration Updates

DEA Diversion website

Newly Designed
- **Top Tabs**
- **Quick Buttons (blue)**
- **Welcome Buttons**

Scroll down for:
- **In the News**
- **What's New**
- **Email updates**

www.DEAdiversion.usdoj.gov

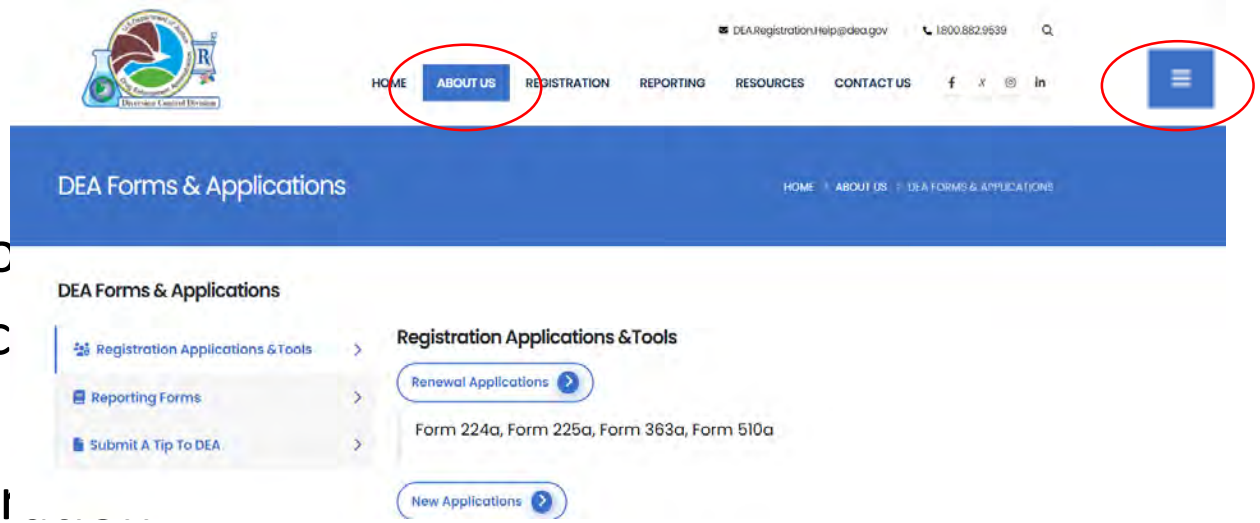


DEA Diversion website

ABOUT US

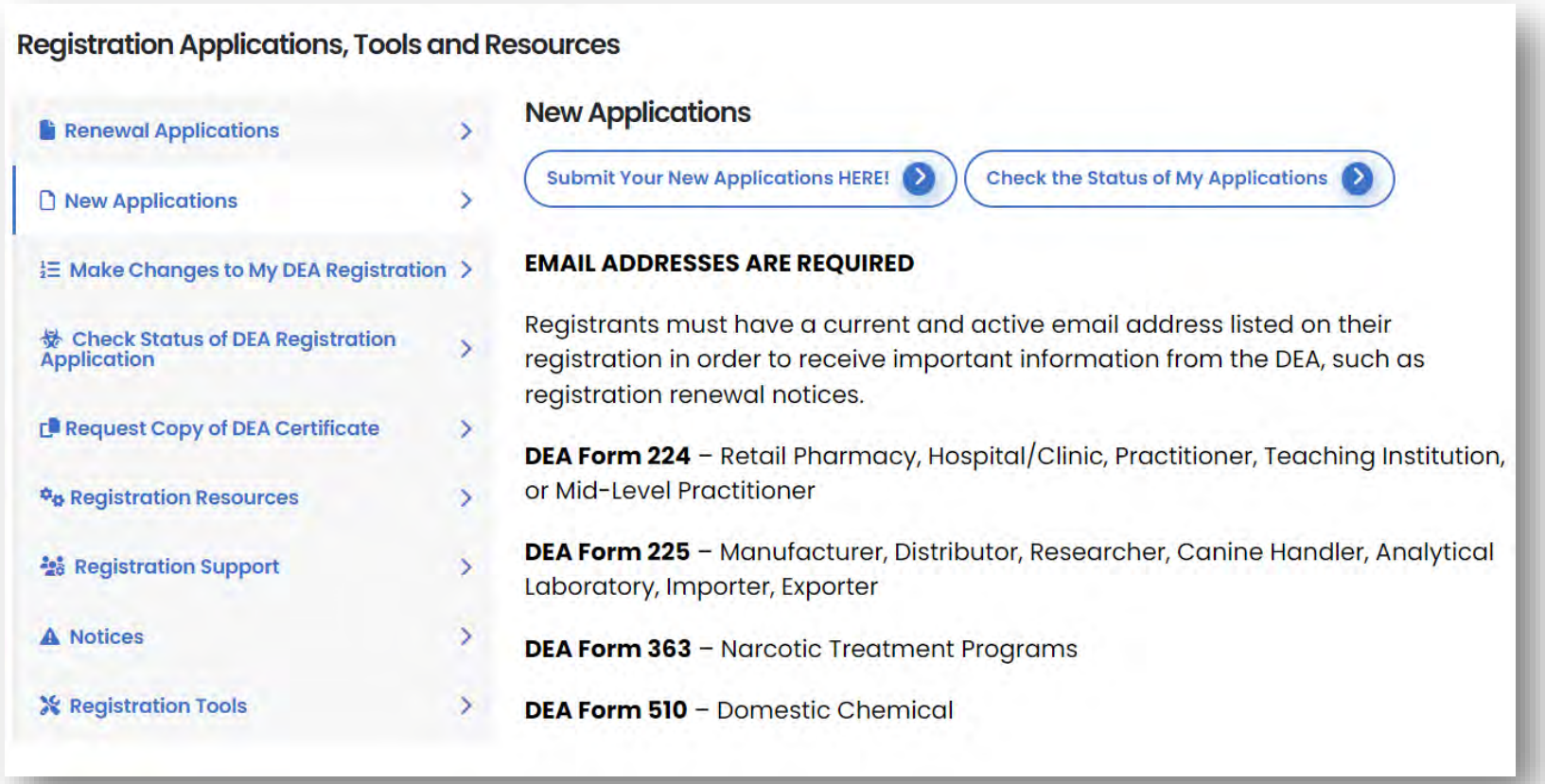
DEA Forms & applications

- Registration Applications
- Check the status of my applicatic
- Request Copy of Application/Rec
- Request Copy of DEA Certificate
- Make Changes to My DEA Regist
- Registration for disposal
- Registration Validation Toolset
- Order Form Request (DEA Form 222)
- CSOS



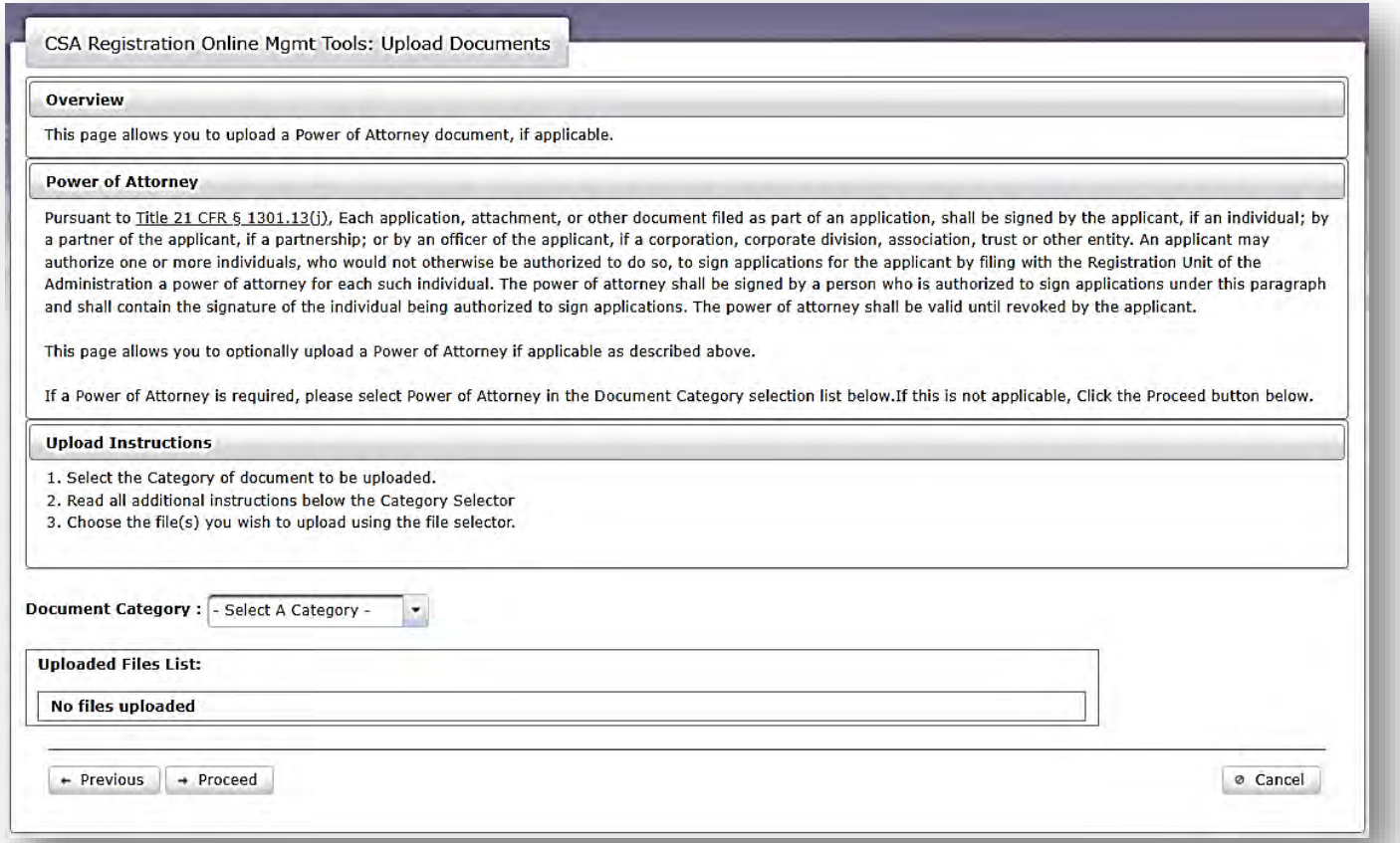
DEA Applications

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.

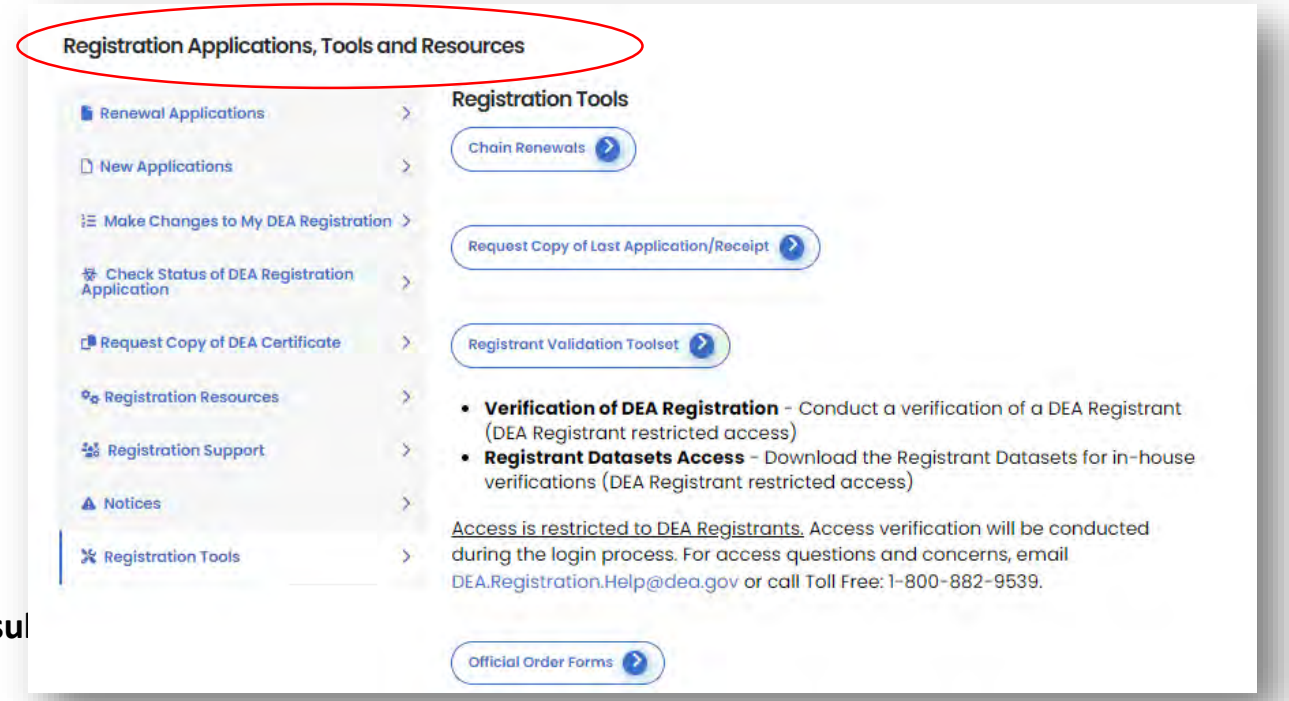


DEA Certificates and Receipts

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.



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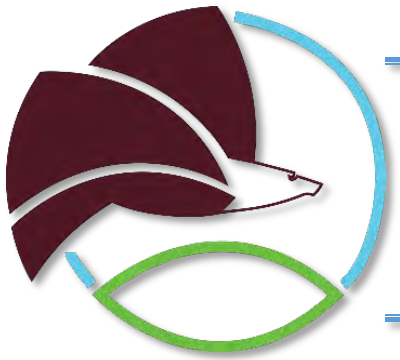


Security Enhancements

Security Implementations

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 Implementations

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.

Security Implementations

Multi-Factor Authentication:

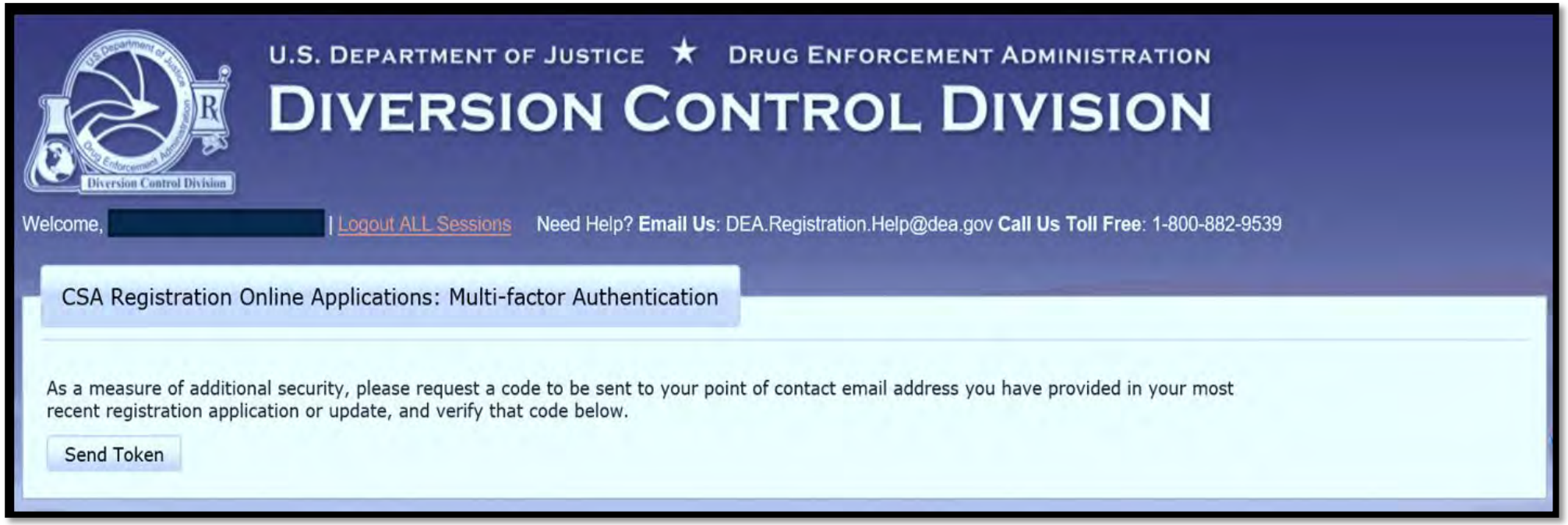
This security feature is necessary for DEA to continue to keep our Registrants' Personally Identifiable Information safe and secure.

- 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.

Security Implementations

Multi-Factor Authentication – Validation Token:



Security Implementations

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

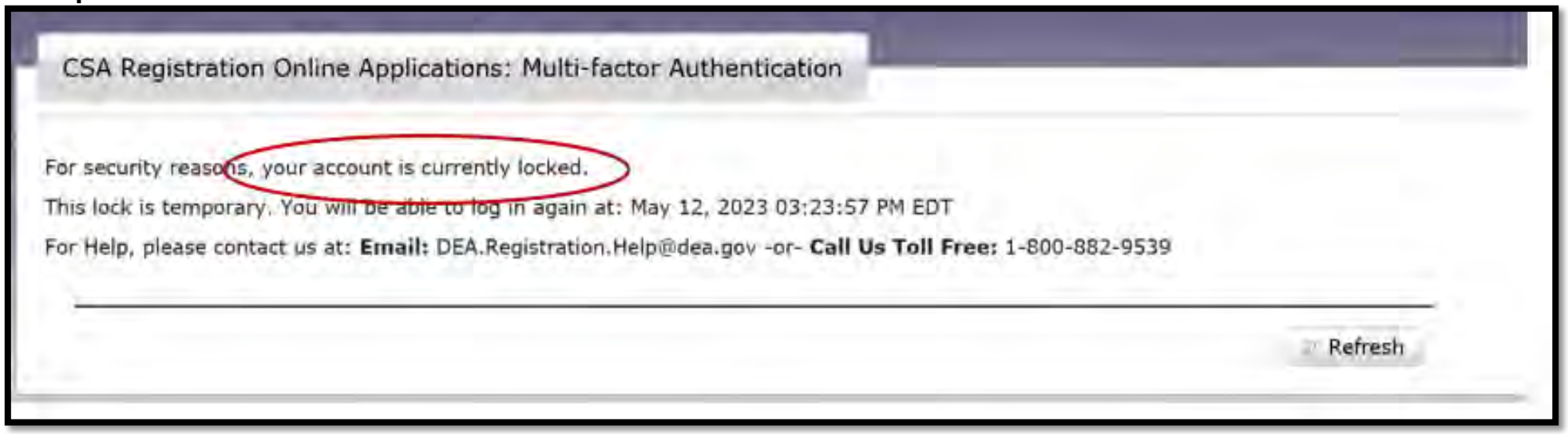
3AV5JF3D

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

Security Implementations

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.



Security Implementations

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:

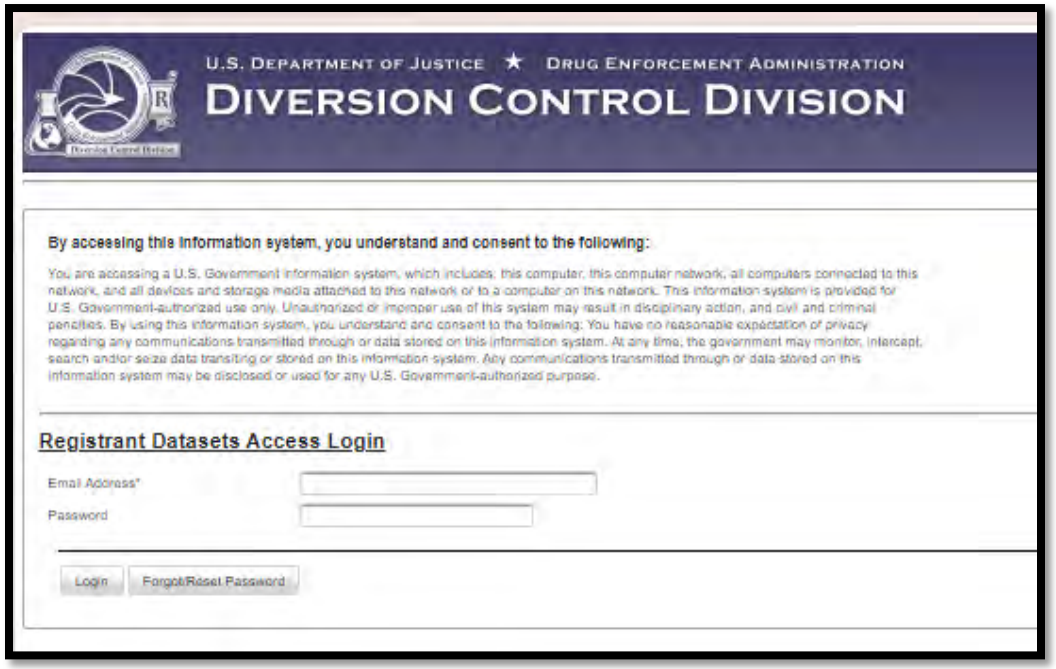
- **Access must be applied for annually**
- **RDA access requires a login & password**
- **To obtain an application or submit the completed form and any supporting documentation e-mail DEA.CSARDA@dea.gov**

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 self-designed 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**

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.**

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.

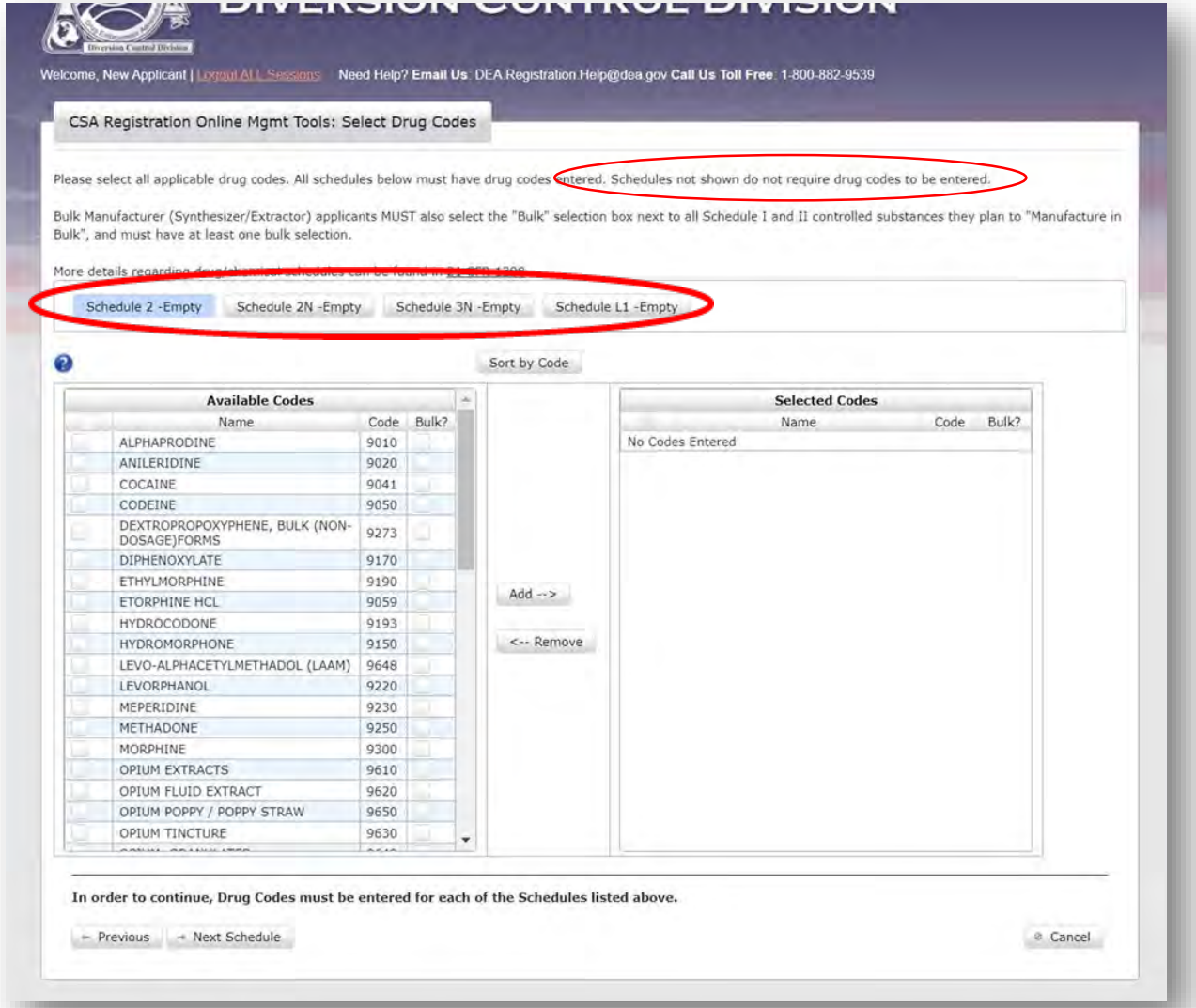
Renewals can be completed online at: www.DEAdiversion.usdoj.gov

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.

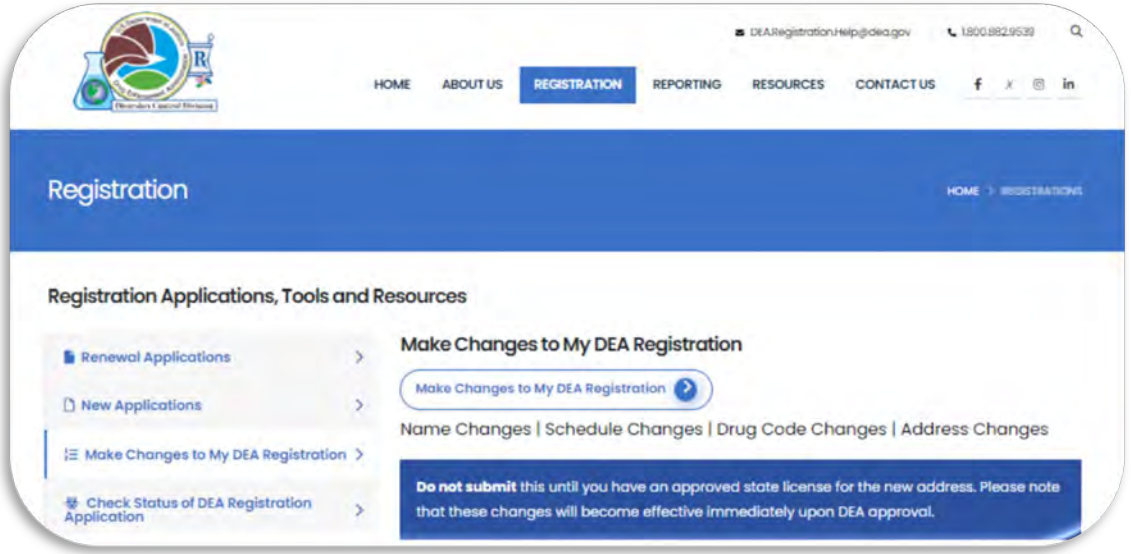


When can I modify my DEA registration?

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.

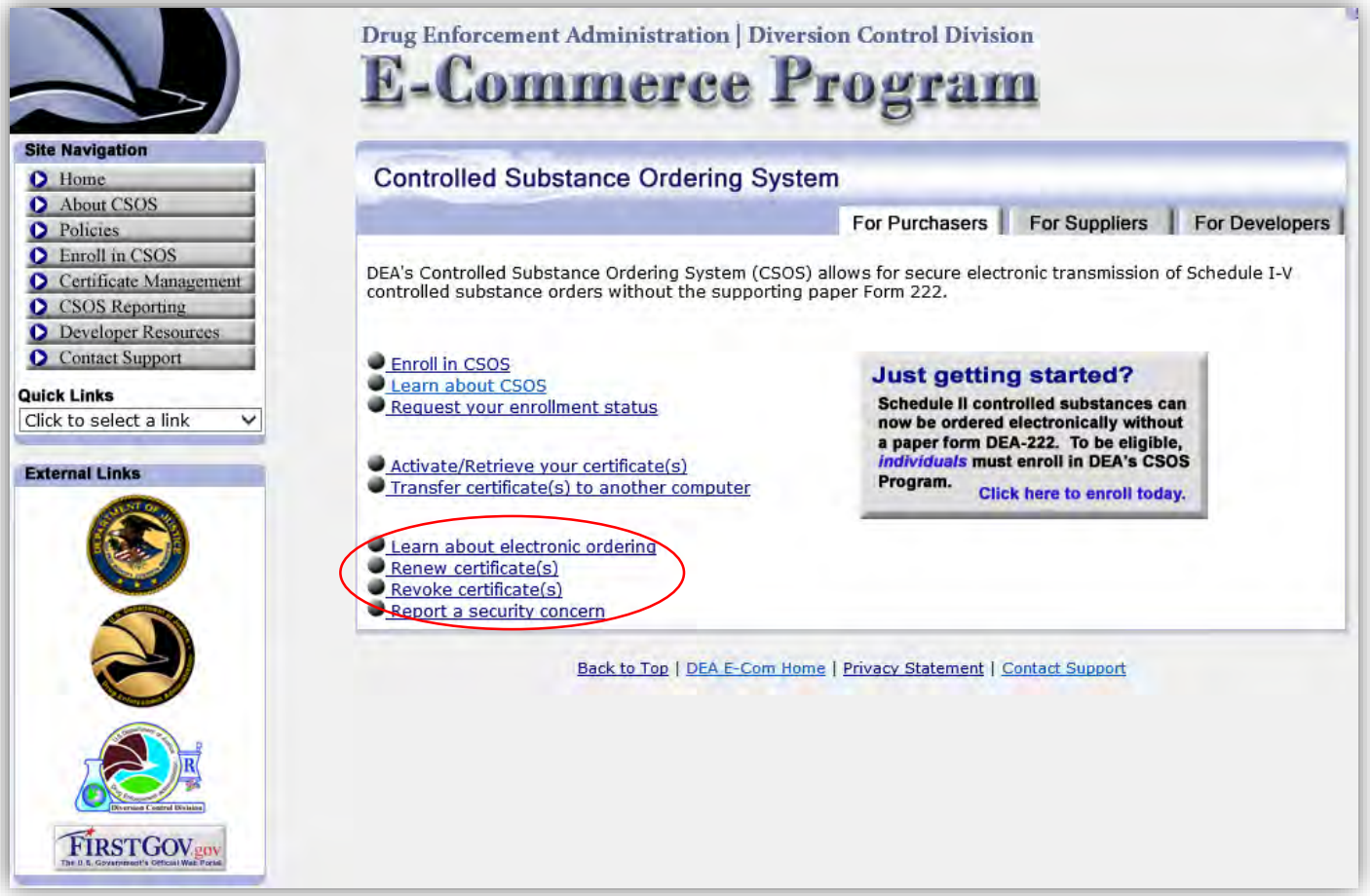
21 CFR § 1311.30(e) - Requirements for Storage and Usage

“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)



www.deaecom.gov

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

Assistance with Registration Matters

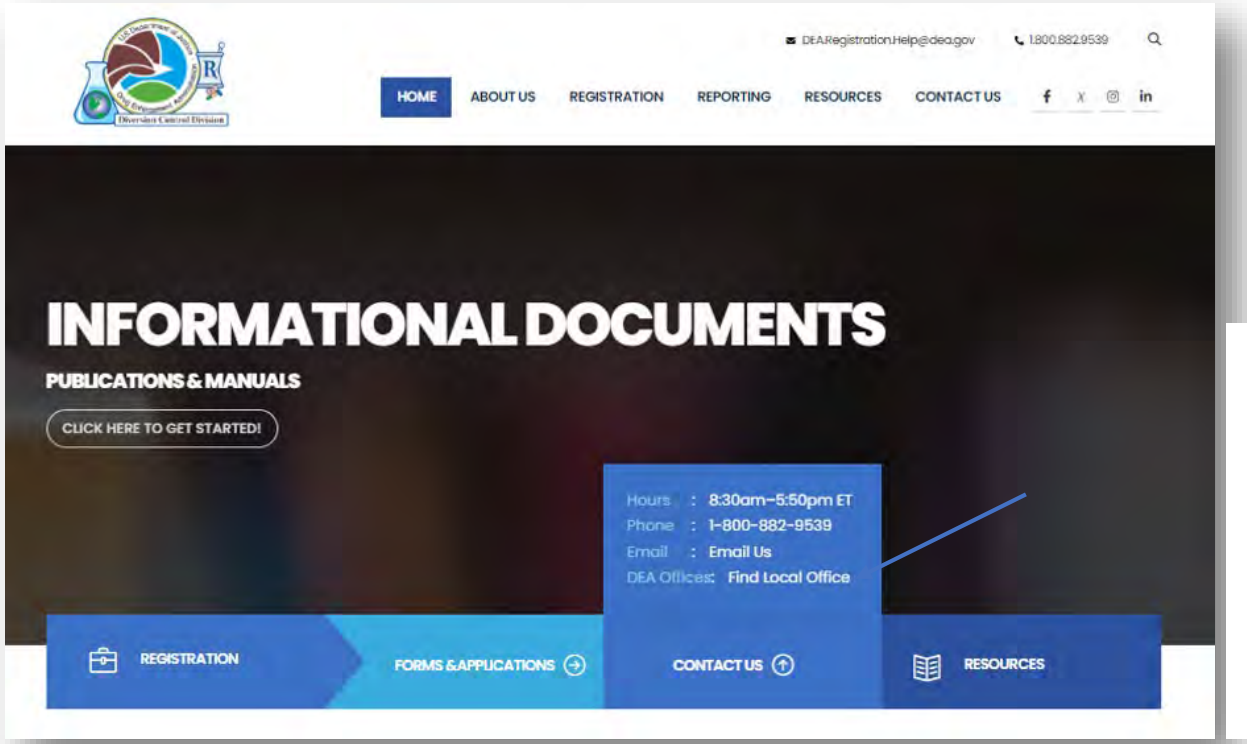
Assistance with Registration Matters

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

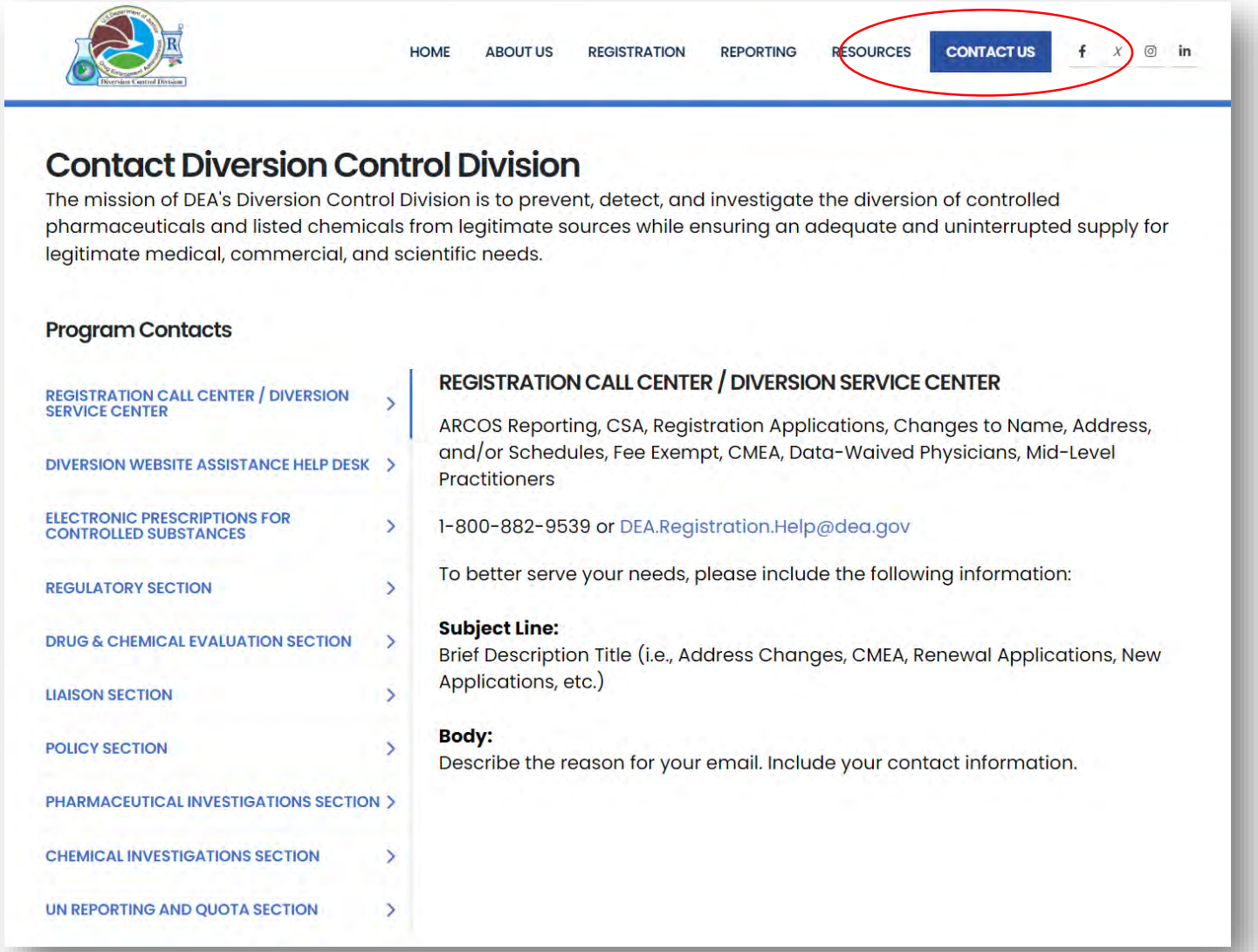
DEA Headquarters
Diversion Control Division
Registration and Business Operations Section (DRR)

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


HOME
ABOUT US
REGISTRATION
REPORTING
RESOURCES
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
DIVERSION WEBSITE ASSISTANCE HELP DESK
ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES
REGULATORY SECTION
DRUG & CHEMICAL EVALUATION SECTION
LIAISON SECTION
POLICY SECTION
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:
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.

Thank You!

Holly Farrington
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United States Drug Enforcement Administration
Washington D.C.

Ofc. 571.324.7471
Holly.M.Farrington@DEA.GOV