Drug Enforcement Administration | Office of Diversion Control

E-Commerce Program



CSOS Subscriber Manual Internet Explorer Version

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1 CSOS Overview

DEA's Controlled Substance Ordering System (CSOS) allows for secure electronic transmission of controlled substance orders without the supporting paper Form 222. Since some DEA (Drug Enforcement Administration) registrants may not wish to take advantage of the new regulations allowing electronic ordering, DEA will leave current regulations and current paper ordering processes in place. The adoption of CSOS standards is the only allowance for the electronic transmission of Schedule I and II controlled substance orders.

Each individual requesting the ability to sign electronic orders for controlled substances must enroll with DEA. This Subscriber Manual documents enrollment with DEA in the CSOS program as well as assistance with certificate acquisition and management. Once a CSOS subscriber has enrolled with DEA and attained his/her digital certificate(s), he/she may place electronic orders of controlled substances from participating suppliers/wholesalers using CSOS approved ordering software.

1.1 CSOS Certificates

1.1.1 CSOS Signing Certificates

Each CSOS Signing Certificate issued by the DEA's CSOS Certificate Authority contains identification information specific to an individual subscriber and his/her associated DEA Registration. Each individual requesting the ability to *sign* electronic CI and CII controlled substance orders must obtain his/her own CSOS Signing Certificate. Each Signing Certificate is specific to one DEA Registration number for one individual.

Multiple Signing Certificates must be requested for applicants requiring the ability to sign electronic CI and CII controlled substance orders for multiple DEA Registration numbers. Multiple Certificates may be requested by completing Registrant List Addendum Application forms (form DEA-254). Addendum forms should be attached to and submitted with a CSOS enrollment package.

1.1.2 CSOS Administrative Certificates

CSOS Administrative Certificates are issued to CSOS Coordinators (see Section 1.2.2). Each CSOS Coordinator, including CSOS Registrants (see Section 1.2.1) serving the role of Coordinator, is issued one CSOS Administrative Certificate. The Administrative Certificate may be used for digitally signing electronic communications, but is not valid for signing electronic orders for controlled substances.

1.2 CSOS Subscriber Roles

Each CSOS applicant serves a specific role and must select a corresponding application form. This Subscriber Manual contains enrollment instructions in Sections 2 and 3 that are specific to each subscriber role. While the roles have overlapping responsibility, each applicant should submit a CSOS application for only one role per DEA Registration.

1.2.1 Registrant

The CSOS DEA Registrant is defined as the *individual* who signed or is authorized to sign the most recent DEA Registration application (Form DEA-223). Typically, the Registrant is also the individual who grants Power of Attorney for controlled substance ordering. Only the individual who signed or is authorized to sign the organization's most recent DEA Registration application may apply for a CSOS Certificate as a Registrant. The Registrant is typically an officer or owner of the organization.

A Registrant completes form DEA-251 where he/she must name a Principal Coordinator as a trusted and recognized individual for administering CSOS Certificates to CSOS applicants for the DEA Registration number(s) listed on his/her application. The Registrant may choose to serve the role of Principal Coordinator and may indicate so by naming him/herself Principal Coordinator on Form DEA-251. Conversely, the Registrant may delegate responsibility by naming an individual to serve as Principal Coordinator. The delegated Principal Coordinator *must* enroll, or already be enrolled, in CSOS by submitting Form DEA-252.

One CSOS Signing Certificate will be issued to the Registrant subscriber for each DEA Registration number requested on his/her application package. Each Signing Certificate may be used *by the certificate owner only* for digitally signing controlled substance orders without a supporting paper form 222.

If electing to serve the role of Principal Coordinator, the Registrant subscriber is issued one CSOS Administrative Certificate in addition to the CSOS Signing Certificate(s). The CSOS Administrative Certificate may be used for communication purposes including digitally signing E-mail communications.

All subscriber roles may be issued CSOS Signing Certificates. An individual, not serving the role of Registrant or Coordinator, who requires the ability to sign electronic controlled substance (CI and CII) orders may enroll as a CSOS Power of Attorney after being authorized by the individual serving as CSOS Coordinator for the requested DEA Registration number(s).

1.2.2 Coordinator

A Principal Coordinator must enroll for each DEA Registration number participating in CSOS (i.e., using electronic ordering). The Principal Coordinator is the organization's primary CSOS contact for the DEA Registration number(s) identified on his/her application. The Principal Coordinator applicant may be any individual employed by the organization and must be designated by the Registrant. A Registrant may designate *one* Principal Coordinator per DEA Registration number or the Registrant may serve the role of Coordinator him/herself.

Optionally, an organization may identify an Alternate Coordinator. Individuals acting as Alternate Coordinator shall serve as that organization's secondary CSOS point-of-contact for the DEA Registration number(s) identified on his/her application. Alternate Coordinator applicants may be any individuals employed by the organization. A Registrant may designate *one* Alternate Coordinator per DEA Registration number.

Principal and Alternate Coordinators serve as the Local Registration Authority (LRA) for the DEA Registration numbers they are responsible for. As an LRA, the Coordinator verifies the identity and authorization of organization personnel applying for CSOS Certificates. Power of Attorney Certificate applications must be signed by a Coordinator as an indication that, as the LRA, the Coordinator has authorized the POA applicant to obtain a CSOS Signing Certificate.

Principal and Alternate Coordinator subscribers are issued one CSOS Administrative Certificate each to be used for communication purposes. Should the Principal or Alternate Coordinator require the authority to sign controlled substance orders, he/she must indicate so on his/her CSOS application (Form DEA-252). If signing authority is requested, and proof of Power of Attorney is provided, the approved Coordinator applicant is issued one CSOS Signing Certificate for each DEA Registration number indicated on his/her application. A CSOS Signing Certificate may be used for signing controlled substance orders for the DEA Registration number it is associated with. As certificates are only issued to individuals, only the individual owner of the CSOS Signing Certificate may use the certificate for signing electronic orders of controlled substances.

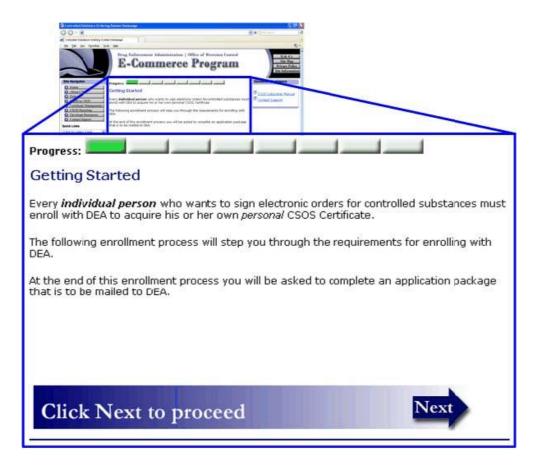
1.2.3 Power of Attorney (POA)

A Power of Attorney (POA) is a non-administrative individual requiring the ability to sign electronic orders for controlled substances. POA applicants must hold a valid Power of Attorney (a letter granting POA from the Registrant) to sign controlled substance orders for the DEA Registration number(s) identified on their application. The CSOS Coordinator for the DEA Registration number(s) indicated on the CSOS POA's application (Form DEA-253) must verify the CSOS POA applicant's identity and the POA applicant's authority to sign controlled substance orders. An approved CSOS POA is issued one CSOS Signing Certificate for each DEA Registration number for which controlled substance order signing authority is requested. As certificates are only issued to individuals, only the individual owner of the CSOS Signing Certificate may use the certificate for signing electronic orders of controlled substances.

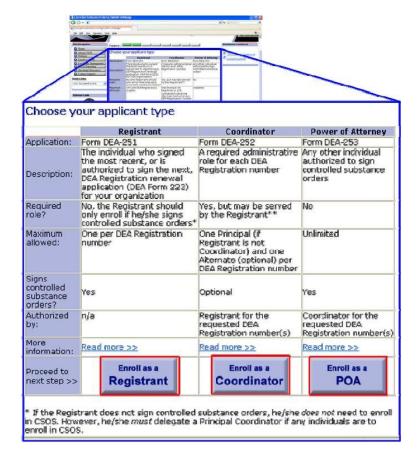
2 CSOS Enrollment

Individuals requesting the ability to participate in the CSOS program must enroll via the DEA Office of Diversion Control's E-Commerce Program Website (www.DEAecom.gov). The enrollment process found on this Site allows the applicant to complete the appropriate CSOS enrollment application, which must be postal mailed to DEA along with supporting documentation.

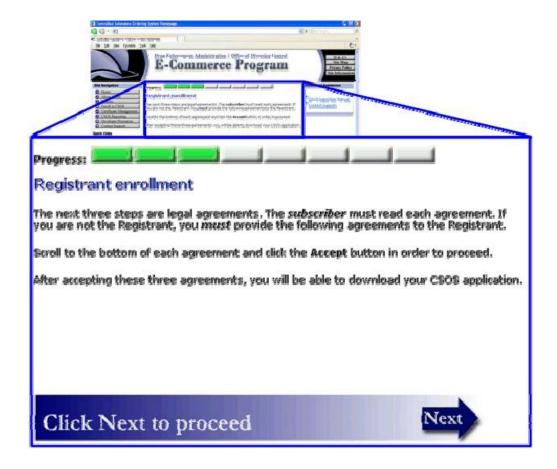
1. Access the CSOS enrollment process at www.DEAecom.gov/applycert.html . Please read this important information and click the Next button when finished.



2. Select the appropriate applicant type based on the information provided on this Web page and/or this Subscriber Manual. Click the associated enrollment button at the bottom of the page to proceed to the next step.

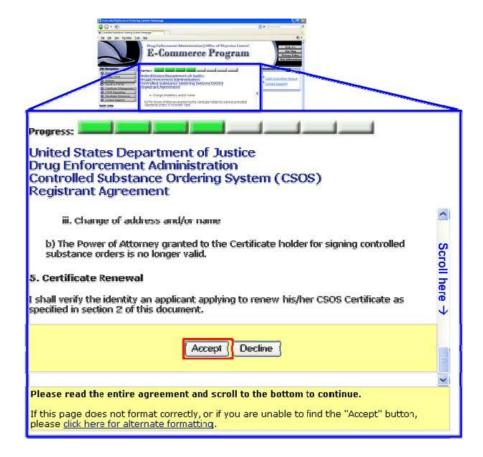


3. Please read this important enrollment information and click the **Next** button when finished.

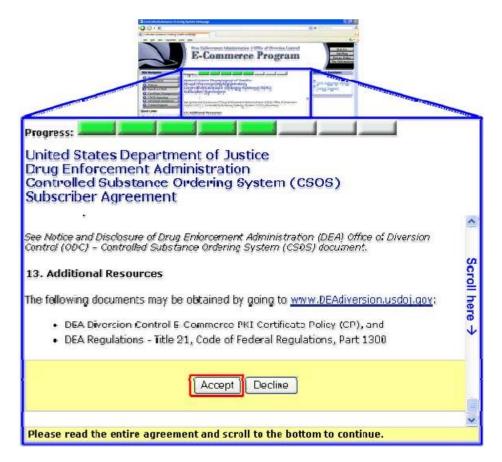


4. This Registrant Agreement outlines the responsibilities of each CSOS Registrant and Coordinator subscribers with regards to his/her administrative participation in the CSOS program. When submitting a CSOS Registrant (DEA-251) or Coordinator (DEA-252), the applicant asserts that he/she has read, understood, and accepted this Registrant Agreement. Please scroll to the bottom of the Agreement and click the **Accept** button to continue.

<u>Note</u>: This agreement is not required for CSOS POA applicants. When proceeding through the POA Enrollment flow, this agreement is not provided.



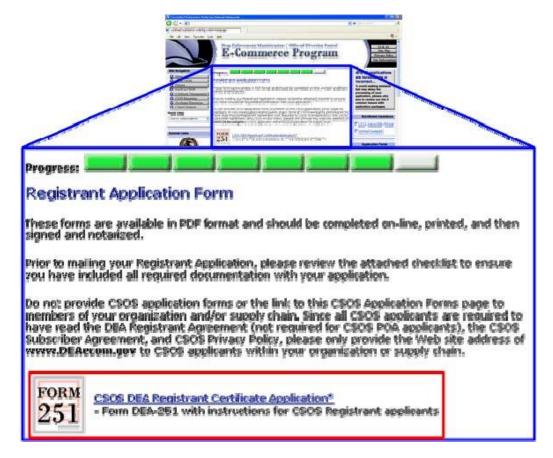
5. This CSOS Subscriber Agreement outlines the responsibilities of all CSOS Subscribers regarding participation in the CSOS program. When submitting a CSOS Registrant (DEA-251), Coordinator (DEA-252), or Power of Attorney (DEA-253) application, the applicant asserts that he/she has read, understood, and accepted this Subscriber Agreement. Please scroll to the bottom of the Agreement and click the **Accept** button to continue.



6. The CSOS Privacy Policy outlines the collection and protection of information relating to the CSOS Program. When submitting a CSOS Registrant (DEA-251), Coordinator (DEA-252), or Power of Attorney (DEA-253) application, the applicant asserts that he/she has read, understood, and accepted this Privacy Policy. Please scroll to the bottom of the Policy and click the <u>Accept</u> button to continue.



7. The applicant's CSOS Certificate Application form is available on this page. Click the link displayed below to open form DEA-251 for Registrant, DEA-252 for Coordinator, or DEA-253 for POA applicants.



- 8. The appropriate CSOS Certificate Application (DEA-251, DEA-252, or DEA-253) will open in Adobe Acrobat Reader. Aside from rare circumstances, each CSOS applicant should submit *only one* CSOS application form.
 - Assistance with completing the application form may be found in Section 3 of this Subscriber Manual. Important instructions and a checklist are included with the application.
 - Do not submit a CSOS Certificate Application without supporting documentation, as listed on the attached Application Checklist.
 - Applicants requesting to be associated with multiple DEA Registration Numbers are required to submit addition information, as documented in this Subscriber Manual's section "Addendum Form DEA-254 and Bulk Enrollment."
- 9. Each CSOS Certificate Application is completed, printed, signed, and notarized (if required) as outlined in the "Certificate Application Form Assistance" section of this Subscriber Manual. Once printed, click the <u>Next</u> button on the CSOS Enrollment web page.

Click Next to proceed



10. The last step of the Enrollment process provides important information to the Subscriber concerning the rest of the Enrollment process after the CSOS Certificate

Application package has been submitted to DEA. This page may be accessed from the following addresses:

- Registrant Applicants: www.DEAecom.gov/forms/reg/nextreg.html
- Coordinator Applicants: www.DEAecom.gov/forms/coord/nextcoord.html
- POA Applicants: www.DEAecom.gov/forms/poa/nextpoa.html

3 Certificate Application Form Assistance

Aside from rare scenarios, each applicant to the CSOS program should submit only one CSOS Certificate Application form. The form submitted varies depending on the applicant's role, as explained in the CSOS Enrollment flow on www.DEAecom.gov. Each application form includes detailed instructions for completing the form, while this section of the Subscriber Manual elaborates on those instructions.

Important notes:

- Each individual person requesting the ability to sign electronic orders for controlled substances must submit an application form.
- The applicant must complete only one application form (DEA-251, DEA-252, DEA-253) unless instructed otherwise by DEA.
- The Certificate Application form is only one of the required documents for enrollment in the CSOS Program. Please review the checklist included on the last page of each application form. Section 3.5 of this Subscriber Manual summarizes the documents that must be submitted in a complete CSOS application package.
- Please reference section 3.4 of this Subscriber Manual if applying using more than one DEA Registration number.

3.1 Registrant Application / DEA-251

All Certificate Applications should be typed electronically into the form and not handwritten. An explanation of each field on the form is included with the Application.

3.1.1 DEA-251 Section 1 – Applicant Information

Important notes:

- All fields must be completed. Please reference the instructions included with the applications or contact DEA Diversion E-Commerce Support if you have any questions.
- The "Applicant" is the Registrant who has signed, or was authorized to sign, the most recent application for DEA Registration.
- The Applicant completes only one Form DEA-251. Additional DEA Registration numbers may be listed on an Addendum Form DEA-254.
- The Applicant lists him/herself as the Coordinator, or delegates this role to another individual enrolling (or already enrolled) as Principal Coordinator.

CSOS DEA Registrant Certificate Application

This application must be completed by the individual who signed the most recent application for DEA Registration (DEA Registrant) or the individual authorized to sign the most recent DEA Registration application. Read instructions before completing. ALL FIELDS ARE REQUIRED.

Section 1 - Applicant Information

Applicant Last Name
SMITH
Applicant First Name
JOHN
MI Applicant SSN Number
JOHN.SMITH@PHARMACY.COM
DEA Registration No. DEA Registrant Name
AA1234567 MAIN STREET PHARMACY
Security Code (e.g. Mother's Maiden Name) Letters only. Remember this code to ensure proper identification when you call the Support Desk. No. of Addendums
JONES 0
Applicant Business Address
123 MAIN STREET
City State Zip
ANYTOWN V A 1 2 3 4 5 1 2 3 4
CSOS Coordinator Last Name (Required - enter either CSOS DEA Registrant applicant or form DEA-252 must be submitted by individual named below)
SMITH
CSOS Coordinator First Name (Required - enter either CSOS DEA Registrant applicant or form DEA-252 must be submitted by individual named below)
JOHN

3.1.2 DEA-251 Section 2 – Applicant Signature

Important notes:

- This applicant signature must be by the Registrant Applicant, who is the individual listed in Section 1 of this Certificate Application (Applicant Last Name/Applicant First Name)
- If this application is not signed, or is signed by the wrong person, the applicant will be denied by DEA and returned to the applicant

Section 2 - Applicant Signature

By signing this document, I am stating that I have read, understand and agree to abide by the rules and regulations conta System Subscriber Agreement and CSOS DEA Registrant Agreement. I am also certifying that the information, statementhis form are true and accurate to the best of my knowledge. I understand presenting false information is a criminal offer	nts, and representations provided by me on
Section 843(a)(4)(A) of Title 21, United States Code, states that any person who knowingly or intentionally furnis application is subject to imprisonment for not more than four years, a fine of not more than \$30,000.00 or both.	hes false or fraudulent information in the
Applicant Signature	Date
Note: This application will be denied and returned if not signed by the DEA Registrant Applicant listed in Section	n 1.

3.1.3 DEA-251 Section 3 – Notary Acknowledgement

Registrant Applications (DEA-251) must be notarized as instructed. Registrant Applications that have not been notarized will be denied by DEA and mailed back to the applicant.

Section 3 - Notary Acknowledgement

4. Identification #1 mus	t be a government ist be a different fo	issued, widely recognized fo	rm of photo ID, such as Driver	seal/stamp the Application form. 's License or Passport. ID #2 does no ID card, utility or tax bill, major
State or Commonwealt	h of	County of	Country	
On	before me.	p	ersonally appeared	
his/her signature on the	e monument me pe	rson executed the instrumen	t in my presence.	
ID #1 (with photograph) ID #2	Туре:	Identifying Number:	Expiration Date:	
ID #1 (with photograph) ID #2 Witness my hand and office	Type:Type:			
ID #1 (with photograph)	Type:Type:	Identifying Number:	Expiration Date:	

3.2 Coordinator Application / DEA-252

All Certificate Applications should by typed electronically into the form and not handwritten. An explanation of each field on the form is included with the Application.

3.2.1 DEA-252 Section 1 – Applicant Information

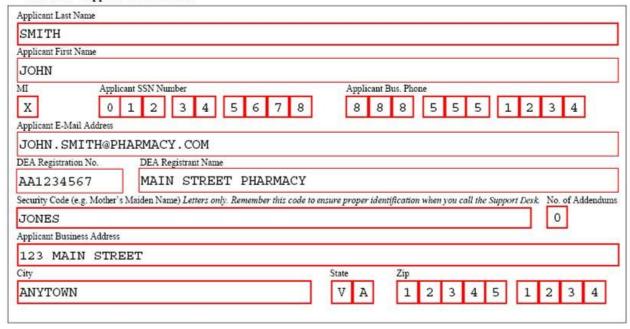
Important notes:

- All fields must be completed. Please reference the instructions included with the applications or contact DEA Diversion E-Commerce Support if you have any questions.
- The "Applicant" is the individual applying to be either the Principal or Alternate Coordinator for the associated DEA Registration numbers and whom the Registrant for those same DEA Registration numbers will authorize.
- The Applicant completes only one Form DEA-252. Additional DEA Registration numbers may be listed on an Addendum Form DEA-254.

CSOS Principal Coordinator/Alternate Coordinator Certificate Application

This application is for individuals applying to serve the role of CSOS Principal Coordinator or CSOS Alternate Coordinator. Applicants who hold a valid Power of Attorney (POA) to obtain and sign Schedules I and/or II controlled substance orders for the DEA Registrant(s) identified will receive a CSOS Signing Certificate. Read instructions before completing. ALL FIELDS ARE REQUIRED.

Section 1 - Applicant Information



3.2.2 DEA-252 Section 2 – Applicant Classification

One Principal Coordinator and one Alternate Coordinator may be enrolled in CSOS per DEA Registration number. Please indicate whether the Coordinator Applicant is to be the Principal or Alternate.

Important notes:

- The Principal Coordinator is a required role for any DEA Registration participating in CSOS
- The Registrant may indicate on his/her Certificate Application (DEA-251) that he/she will be the Principal Coordinator. In this scenario, only one other individual may enroll as Coordinator, and must be the Alternate. The Registrant should not complete a Form DEA-252.

The Coordinator Applicant must indicate whether he/she requests a CSOS Signing Certificate for signing electronic orders for controlled substances. If not requested, the Applicant will assume solely an administrative role and be issued a CSOS Administrative Certificate only.

• Coordinator Applicants requesting a CSOS Signing Certificate must provide a photocopy of their letter granting Power of Attorney for controlled substance ordering issued by the Registrant for the associated DEA Registration numbers.

1.	Are you applying as Principal Coordinator Alternate Coordinator
2.	Do you also wish to obtain a CSOS Signing Certificate for signing controlled substance orders for the identified DEA Registrant(s)?
	Yes No No

3.2.3 DEA-252 Section 3 – Applicant/Notary Signature

Both the Coordinator Applicant and a Notary must sign the Coordinator Certificate Application. Applications that are missing a signature, or are signed by the incorrect person, will be denied by DEA and returned to the applicant.

- The Applicant Signature must be that of the *Coordinator Applicant* listed in Section 1 of this Coordinator Certificate Application (DEA-252).
- The Notary is the individual notarizing Section 6 of this Coordinator Certificate Application (DEA-252).

Section 3 - Applicant/Notary Signature

Date
Date

3.2.4 DEA-252 Section 4 – DEA Registrant's Affirmation of Delegation of Coordinator

This section of the Coordinator Certificate Application must contain the contact information and name of the DEA Registrant for the DEA Registration numbers associated with this Application. The Registrant is the *individual* who signed, or was authorized to sign, the most recent application for DEA Registration for the DEA Registration numbers associated with this application. Registrant enrollment in CSOS is optional and may be limited to Registrants who sign controlled substance orders.

• This Coordinator Certificate Application will be denied by DEA and returned to the Applicant if not signed by the DEA Registrant in Section 4.

Section 4 - DEA Registrant's Affirmation of Delegation of Coordinator

Organization Name											
MAIN STREET PHARMACY											
Organization Address											
123 MAIN STREET											
City	State		Zip								
ANYTOWN	V	A	1	2	3	4	5	1	2	3	4
As the individual who signed the most recent application for I Registration for the DEA Registration numbers submitted wit Coordinator for the above organization and identified DEA Registration.	h this application I certify the										
Registration for the DEA Registration numbers submitted wit	th this application I certify the egistrant(s).	applica	nt listed in	Section				gated to			
Registration for the DEA Registration numbers submitted wit Coordinator for the above organization and identified DEA Re Signature of DEA Registrant	th this application I certify the egistrant(s).	applica	nt listed in	Section				gated to	act as		
Registration for the DEA Registration numbers submitted wit Coordinator for the above organization and identified DEA Re Signature of DEA Registrant Last Name (Print)	th this application I certify the egistrant(s).	applica	nt listed in	Section				gated to	act as		
Registration for the DEA Registration numbers submitted wit Coordinator for the above organization and identified DEA Re Signature of DEA Registrant	th this application I certify the egistrant(s).	applica	nt listed in	Section				gated to	act as		
Registration for the DEA Registration numbers submitted wit Coordinator for the above organization and identified DEA Resistrant	th this application I certify the egistrant(s).	applica	nt listed in	Section				gated to	act as		

3.2.5 DEA-252 Section 5 - Applicant Signature

Important notes:

- This applicant signature must be by the *Coordinator Applicant*, who is the individual listed in Section 1 of this Certificate Application (Applicant Last Name/Applicant First Name).
- If this application is not signed, or is signed by the wrong person, the applicant will be denied by DEA and returned to the applicant.

Section 5 - Applicant Signature

By signing this document, I am stating that I have read, understand and agree to abide by the rules System Subscriber Agreement and the CSOS DEA Registrant Agreement. I am also certifying tha on this form are true and accurate to the best of my knowledge. I understand presenting false infor	t the information, statements, and representations provided by me
Section 843(a)(4)(A) of Title 21, United States Code, states that any person who knowingly of the application is subject to imprisonment for not more than four years, a fine of not more than $f(x)$ to $f(x)$ to $f(x)$ the section $f(x)$ that $f(x)$ is $f(x)$ the section $f(x)$ to $f(x)$ the section $f(x)$ that $f(x)$ is $f(x)$ the section $f(x)$ that $f(x)$ is $f(x)$ that $f(x)$ that $f(x)$ is	
Applicant Signature	Date
Note: This application will be denied and returned if Section 5 does not include the signature of	f the Coordinator Applicant listed in Section 1.

3.2.6 DEA-252 Section 6 - Notary Acknowledgement

Coordinator Certificate Applications (DEA-252) must be notarized as instructed. Coordinator Certificate Applications that have not been notarized will be denied by DEA and mailed back to the applicant.

Section 6 - Notary Acknowledgement

State or Commonwealt	h of	County of	Country	
		County of		
On	before n		personally appeared	o forms of identification listed below
	Type:	Identifying Number:	Expiration Date:	
D#2 Vitness my hand and offici	Type:			
ID #1 (with photograph) ID #2 Witness my hand and offici Notary's Signature: Notary's Name (Print or Ty Notary's Address:	Type:ial seal.			Access of the Ac

3.3 Power of Attorney Application / DEA-253

All Certificate Applications should by typed electronically into the form and not handwritten. An explanation of each field on the form is included with the Application.

3.3.1 DEA 253 Section 1 – Applicant Information

Important notes:

- All fields must be completed. Please reference the instructions included with the applications or contact DEA Diversion E-Commerce Support if you have any questions.
- The "Applicant" is the individual applying as a CSOS Power of Attorney for the associated DEA Registration numbers and whom a Coordinator for those same DEA Registration numbers will authorize.
- The Applicant completes only one Form DEA-253. Additional DEA Registration numbers may be listed on an Addendum Form DEA-254.

Applicant Last Name DAVIS Applicant First Name SAM Applicant SSN Number Applicant Bus. Phone МІ X 0 0 0 1 2 3 4 5 6 8 8 5 5 5 1 2 3 5 Applicant E-Mail Address SAM.DAVIS@PHARMACY.COM DEA Registration No. DEA Registrant Name AA1234567 MAIN STREET PHARMACY Security Code (e.g. Mother's Maiden Name) Letters only. Remember this code to ensure proper identification when you call the Support Desk. No. of Addendums

0

Section 1 - Applicant Information

3.3.2 DEA-253 Section 2 – Applicant Signature

Important notes:

johnson

- This applicant signature must be by the *Power of Attorney Applicant*, who is the individual listed in Section 1 of this Certificate Application (Applicant Last Name/Applicant First Name).
- If this application is not signed, or is signed by the wrong person, the applicant will be denied by DEA and returned to the applicant.

Section 2 - Applicant Signature

By signing this document, I am stating that I have read, understand and agree to abide by the System Subscriber Agreement. I am also certifying that the information, statements, and rep best of my knowledge. I understand presenting false information is a criminal offense and is	resentations provided by me on this form are true and accurate to the
Section $843(a)(4)(A)$ of Title 21, United States Code, states that any person who know in the application is subject to imprisonment for not more than four years, a fine of not more than four years, a fine of not more than four years.	
Applicant Signature	Date
Note: This application will be denied and returned if not signed by the Power of Attorn	ney Applicant listed in Section 1.

3.3.3 DEA-253 Section 3 – CSOS Coordinator Affirmation of Applicant Identity Verification

The Power of Attorney Certificate Application (DEA-253) does not require notarization. The Principal or Alternate Coordinator, acting as Local Registration Authority (LRA), is responsible for verifying the identity and authority of the Power of Attorney Applicant. This Verification is indicated in Section 3 of the DEA-253.

- This signature and name must be that of a *CSOS Coordinator* for the associated DEA Registration numbers.
- Applications missing a signature, or signed by the wrong person, will be denied by DEA and returned to the applicant.

Section 3 - CSOS Coordinator Affirmation of Applicant Identity Verification

As CSOS Principal Coordinator or CSOS Alternate Coordinator for the identity and authorization of the applicant in accordance with the DEA l	
CSOS Coordinator Signature	Date
Last Name (Print)	
SMITH	
First Name (Print)	
JOHN	

3.4 Addendum Form DEA-254 and Bulk Enrollment

3.4.1 Registrant List Addendums

The CSOS Certificate Registrant List Addendum, form DEA-254, may be attached to any CSOS Certificate Application (DEA-251, DEA-252, or DEA-253) for the purpose of associating the individual CSOS Applicant with additional DEA Registration numbers. The Addendum form is simply an attachment to an existing CSOS Certificate Application form/package.

Up to five (5) Addendum forms may be submitted allowing for the listing of 50 DEA Registration Numbers. If the applicant is associated with more than 50 DEA Registration numbers, he/she may bulk enroll as explained in the "Eligibility for Bulk Enrollment" section of this Subscriber Manual.

3.4.1.1 Addendums for Registrants

Please keep in mind that a separate CSOS Signing Certificate will be issued for each DEA Registration number indicated by the Registrant. Registrant Applicants should only enroll in the CSOS Program if the Applicant signs controlled substance orders or is to be the administrator/coordinator for his/her associated DEA Registration numbers. Additionally, bulk enrollment is not recommended for any Registrant Applicant.

3.4.1.2 Addendums for Coordinators

Coordinator Applicants typically request to be the CSOS Coordinator/Administrator for multiple DEA Registration Numbers. This scenario is ideal for organizations with multiple DEA Registration numbers where the Coordinator Applicant(s) performs an administrative role and does not sign controlled substance orders. Please keep in mind that if the Coordinator Applicant requests a CSOS Signing Certificate, one Certificate will be issued for each DEA Registration number associated with the Coordinator's Application package.

3.4.1.3 Addendums for POAs

POA Applicants should use Addendum forms to indicate additional DEA Registration numbers for which the applicant requires a CSOS Signing Certificate for electronic ordering of controlled substances. One CSOS Signing Certificate is issued to the approved applicant for each DEA Registration number indicated on the applicant's form DEA-253 and addendum form DEA-254.

3.4.2 DEA-254 Section 1 – Applicant Information

Enter the information of the CSOS Applicant. The Applicant name must be typed as it appears in Section 1 of the corresponding applicant's form DEA-251, DEA-252, or DEA-253. **All fields are required**.



3.4.3 DEA-254 Section 2 – DEA Registrant List

List the DEA Registration Number and DEA Registrant Name for each Registration the applicant is to be associated with. The Registration (number and name) appearing in Section 1 of the associated form DEA-251, DEA-252, or DEA-253 *should not be included in this list.*

DEA Registration No.	DEA Registrant Name				
AM0000001	MAIN STREET PHARMACY #1				
DEA Registration No.	DEA Registrant Name				
AM0000002	MAIN STREET PHARMACY #2				
DEA Registration No.	DEA Registrant Name				
BM0000001	MAIN STREET PHARMACY #3				
DEA Registration No.	DEA Registrant Name				
DEA Registration No.	DEA Registrant Name				
DEA Registration No.	DEA Registrant Name				
DEA Registration No.	DEA Registrant Name				
DEA Registration No.	DEA Registrant Name				
DEA Registration No.	DEA Registrant Name				
DEA Registration No.	DEA Registrant Name				

3.4.4 DEA-254 Section 3 – Applicant/Notary Signature

Section 3 must contain the signature of the CSOS Applicant. This is the individual named in Section 1 of this form DEA-254 as well as in Section 1 of the associated Certificate Application form DEA-251, DEA-252, or DEA-253.

Registrant and Coordinator applicants must have Section 3 of this DEA-254 signed by the notary who completed either Section 3 of the DEA-251 or Section 6 of the DEA-252. Power of Attorney applicants must have Section 3 signed by a CSOS Coordinator for the associated DEA Registration numbers.

Date
Date

3.4.5 Eligibility for Bulk Enrollment

Applicants requesting to be associated with more than 50 DEA Registration numbers must enroll in the CSOS Program using bulk enrollment. Bulk enrollment replaces the

use of Addendum forms to accommodate organizations that need to obtain a large volume of CSOS Certificates associated with a single applicant. The applicant should contact DEA Diversion E-Commerce Support at 1-877-DEA-ECOM (1-877-332-3266) before submitting a bulk enrollment application.

Bulk Enrollment may be used only when a single applicant is to enroll in the CSOS Program and be associated with more than 50 DEA Registration numbers for administrative or ordering purposes. Additionally, the organization must currently participate in the DEA Chain Renewal program. More information about this process can be found at the following Web page:

• Bulk Enrollment Procedure: www.DEAecom.gov/BulkCrt.html

3.5 Required Attachments

The CSOS Certificate Application is only one of the documents required for CSOS Enrollment. The final page of each CSOS Certificate Application includes a checklist of the required supporting documentation. The following table is a summary of the required documentation for each Certificate Application.

CSOS Applicant Type						
	Registrant	Coordinator	POA			
Certificate Application Form	FORM 251	FORM 252	FORM 253	Each applicant should only submit one application form		
Authorized	N/A Not required	by Registrant (252 section 4)	by Coordinator (253 section 3)	Coordinator and POA Certificate applications must be authorized as instructed		
Notarized	(251 Section 3)	(252 Section 3 and 6)	N/A Not required	Registrant and Coordinator Certificate Applications must be notarized as instructed		
Identification photocopies		V		Two forms of identification are required: 1. A government issued photo ID (Driver's license or passport) 2. A secondary form of ID (pharmacist license, work ID badge, library card)		
DEA Registration Certificate photocopies	V	V	N/A Not required	A photocopy of the DEA Registration Certificate (Form DEA-223) is required for each DEA Registration number		
Power of Attorney letter photocopy	N/A Not required	Required if requesting signing authority		See www.DEAecom.gov/poa.html for more information about Power of Attorney letters		

3.7.2 Enrollment Approval and Certificate Issuance

Upon approval, DEA sends the applicant one E-mail and one postal mailed document for each CSOS Certificate issued. These Activation Notices are to be used *by the applicant* for retrieving his/her CSOS Certificate(s) via DEA's secure certificate retrieval Web page.

For each CSOS Certificate issued:

- An **Access Code** is sent to the applicant via E-mail from regauth@DEAecom.gov to the E-mail address provided on the application
- An **Access Code Password**, a Website address for Certificate retrieval, and Website log in information, is sent via postal mail to the Coordinator, whose address was provided on the Coordinator application. The Principal Coordinator must forward the **unopened** mailed document to the Registrant.

After receiving the retrieval information, the *subscriber* (*certificate owner*) accesses DEA's secure certificate retrieval Website to retrieve his/her CSOS Certificate(s). Instructions for retrieving CSOS Certificates are provided in Section 4 of this Subscriber Manual.

4 Certificate Retrieval

Retrieving (synonymous with activating) a CSOS Certificate creates the digital certificate and stores it in the Internet browser (i.e. Internet Explorer). This certificate may remain in the browser until ordering software is installed on the computer.

- Activate CSOS Certificates on the computer that will be used for electronic ordering of controlled substances. Certificates may be transferred to other computers. To place an electronic order, the certificate will need to be present on the ordering computer.
- Use only Internet Explorer or Firefox browsers. Do not use Netscape, AOL, or MSN browsers. Please contact DEA Diversion E-Commerce Support if this is an issue.
- Only the owner of the certificate may retrieve it.
- Certificates may only be retrieved once.
- Do not disclose the Certificate's password to anyone.

This section discusses the technical requirements and processes for retrieving a CSOS digital certificate. Certificates may be retrieved once the applicant has received an E-mail and a mailed activation notice for the Certificate. One E-mail and postal mailed document pair will be sent for each Certificate.

- 1. CSOS Signing Certificate activation notices contain a DEA Registration number. The E-mail and postal mailed document should be matched based on the certificate owner's name and the DEA Registration number.
- 2. CSOS Administrative Certificate activation notices do not contain a DEA Registration number. The postal mail document contains an **Admin Cert ID Number** rather than the DEA Registration number, while the E-mail activation notice contains an **Organization ID** #.

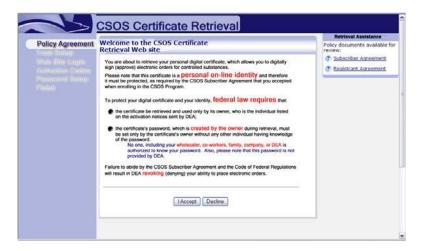
CSOS Administrative Certificate activation notices contain an **Admin Cert ID Number** instead of a DEA Registration number.

4.1 Subscriber Certificate Retrieval Instructions

Once the certificate activation notices have been received, the subscriber (owner of the CSOS certificate) must access DEA's secure certificate retrieval Website and retrieve his/her certificates. Incorrect certificate retrieval may result in an invalid certificate or may compromise the security of the certificate, so please read the instructions in this section carefully.

4.1.1 Policy Agreement

The *owner* of the certificate is required to review the following policy information and click **I Accept** to indicate that he/she understands and agrees to comply with the stated policy.



4.1.2 Trust Setup

DEA's Certification Authority (CA) has three CA Certificates:

- DEA E-Commerce Root CA Certificate
- CSOS Sub CA Certificate
- CSOS Sub CA 2 Certificate

Install the DEA E-Commerce Root CA, CSOS Sub CA, & CSOS Sub CA2 certificates as documented on the side panel of the Web page and in the following steps. These CA certificate installations are required once per ordering computer. If you are unsure whether the certificates have been installed, you may do so again since there is no harm in installing the CA certificates multiple times.

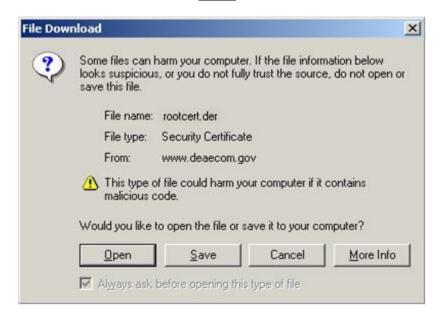
When finished, click the <u>Click to continue after installing all DEA CA Certificate</u> button at the bottom of the screen.

4.1.2.1 DEA E-Commerce Root CA Certificate

1. Click Install the DEA E-Commerce Root CA Certificate.



2. At the File Download screen click **Open**.



3. At the Certificate window on the General tab click Install Certificate.



4. At the Certificate Import Wizard screen, click Next.



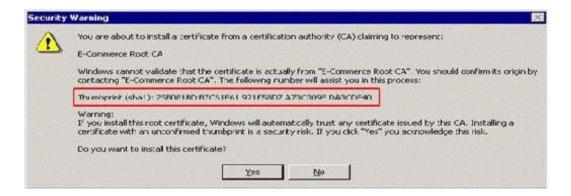
5. At the *Certificate Store* verify that the *Automatically select the certificate store* based on the type of certificate option is selected and click **Next**.



6. At the *Completing the Certificate Import Wizard*, click **Finish**.



- 7. (If prompted) At the *Security Warning* prompt, select \underline{Yes} if the Thumbprint value matches the value below.
 - Thumbprint (sha1): 258081BD B7C61F61 971E58D7 A73C309F DA3CDF40 The Thumbprint is used to verify the authenticity of the E-Commerce Root CA certificate. If the values do not match click $\underline{\textbf{No}}$ and please contact the Support Desk.



8. Click **OK** at the prompt.

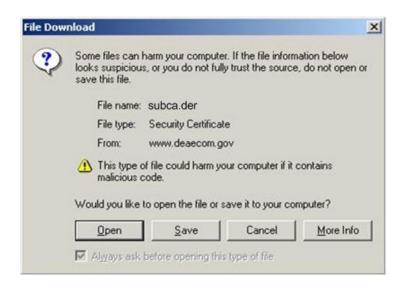


4.1.2.2 CSOS Sub CA Certificate Installation

1. Click **Install the CSOS Sub CA Certificate**.



2. At the *File Download* screen, click **Open**.



3. At the Certificate window on the General tab, click Install Certificate.



4. At the *Certificate Import Wizard* screen, click **Next**.



5. At the *Certificate Store*, verify that the *Automatically select the certificate store* based on the type of certificate option is selected and click <u>Next</u>.



6. At the Completing the Certificate Import Wizard, click Finish.



7. Click **OK** at the prompt.



8. Click **OK** to close the *Certificate* window.

9. Click the <u>Click to continue after installing all four DEA CA Certificates</u>.



4.1.3 Website login



4.1.3.1 Step 1: Certificate Activation Information

In order to retrieve your CSOS certificate, the following items will be needed:

- Access Code located in the E-mail from regauth@DEAEcom.gov
- Access Code Password indicated on the mailed document from DEA

Each certificate has a unique Access Code and Access Code Password. If you have received multiple postal mailed activation notices, then there are multiple certificates to retrieve, each with a different Access Code and Access Code Password.

Match each Certificate's Access Code (the E-mail) with its corresponding Access Code Password (the postal mailed document) using either the DEA Registration number or the Admin Cert ID number located in both the E-mail and Step 1 of the postal mail activation notice.

4.1.3.2 Step Two: Secure Log in Information

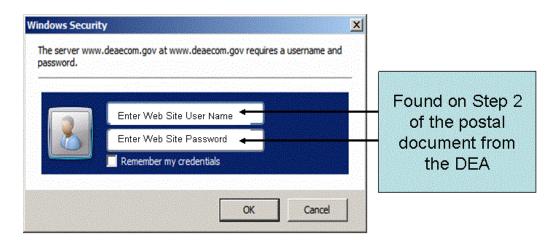
1. Click the **Retrieve a CSOS Certificate** button.



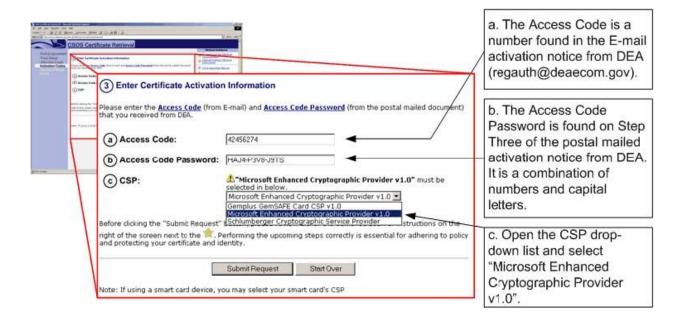
2. Enter the **Website Username** and **Website Password** from Step 2 of the postal mailed activation notice from DEA. The Password is cAsE sEnSiTiVe and may contain special characters such as @, #, and \$.



Step 3 – Use this Access Code Password, along with the Access Code from your E-Mail to activate your certificate Access Code Password: Access Code Password



4.1.4 Enter Certificate Activation Information



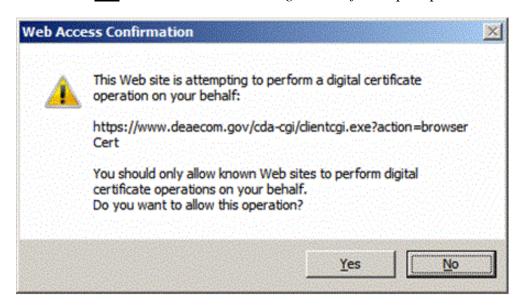
- 1. **Enter the Access Code for this certificate**. The Access Code may be found in the E-mail from DEA (<u>regauth@deaecom.gov</u>) and is specific to this certificate only.
- 2. Enter the Access Code Password for this certificate. The Access Code may be found in Step 3 of the postal mailed document from DEA and is specific to this certificate only. The Access Code Password is a combination of numbers and letters separated by dashes (the dashes are optional).



- 3. **Select "Microsoft Enhanced Cryptographic Provider v1.0"** as the CSP. If not selected, the Website will most likely indicate that an error has occurred.
- 4. Click the **Submit Request** button.

4.1.4.1 Certificate Creation Steps

1. Click the **Yes** button at the *Potential Digital Certificate* prompt.

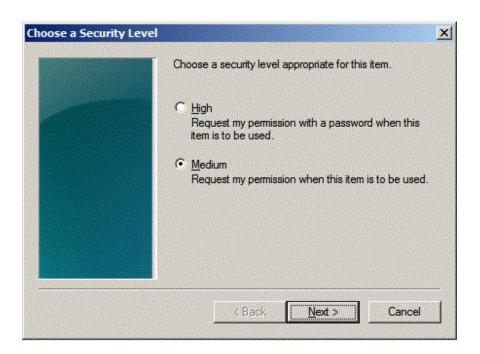


2. Click Set Security Level.

Setting the Security Level will allows for a personal password to be entered to protect the certificate. This password ensures that only the owner of the certificate may use it for electronic ordering.



3. Change the security level to "High" and click the **Next** button.



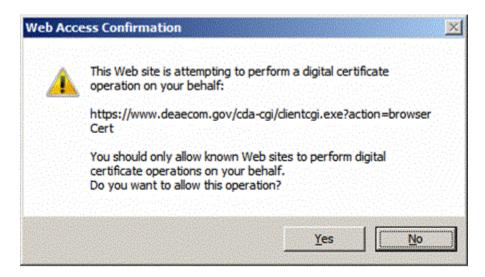
- 4. Enter the name of the certificate owner in the "Password for" text box. This text box will often be grayed out and no text can be entered, which is OK. Create a password of your own to protect the certificate and enter it in the "Password" and "Confirm" text boxes. Once the password has been entered, click the **Finish** button.
- This password is to be entered by the owner of the certificate and must not be shared with anyone. The password is CaSe SenSiTiVe and must not be forgotten.



5. The security level has been set to High. Click the \underline{OK} button to continue.



6. Click the <u>Yes</u> button to add/retrieve your certificate. This prompt may appear up to several times.



7. The below screen indicates that the certificate has been successfully retrieved. This means that the certificate has been created and installed on the computer. At this point, contact your wholesaler or software vendor, or retrieve additional certificates.

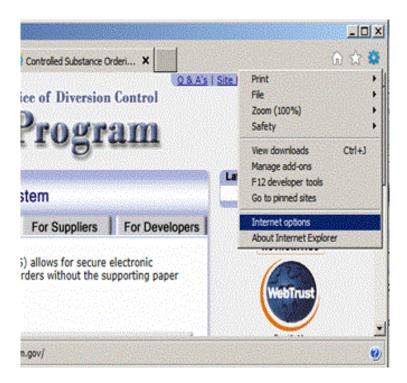


4.2 Certificate Export

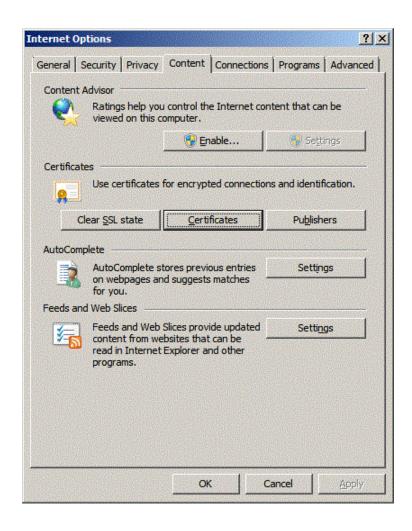
Purpose: These certificate export instructions may be used to copy a certificate from the Internet Explorer certificate store. Once the certificate has been exported it may be backed up, transferred to another computer, or imported into the certificate store of the ordering software.

The owner of the certificate is required to be present for certificate export and is the only person authorized to enter the certificate's password. Certificates exported without the owner present are subject to certificate revocation by DEA.

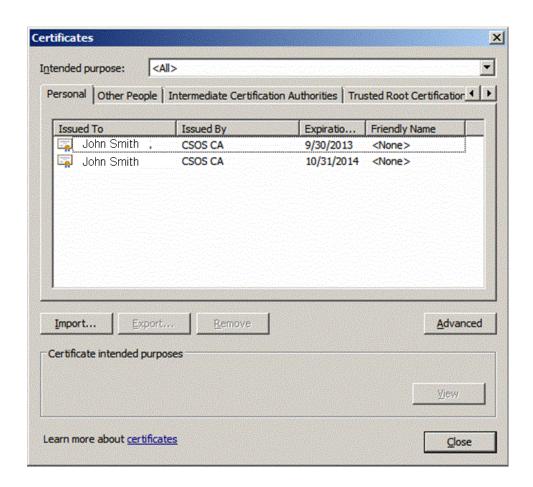
- 1. Open Internet Explorer.
- 2. Open the **Tools** menu and select **Internet Options**.



3. Switch to the **Content** tab and click the **Certificates...** button.



- 4. Select the CSOS Certificate to export and click the **Export** button.
 - CSOS Certificates are issued by "CSOS CA."
 - CSOS Administrative Certificates expire three (3) years from the date of issuance.
 - CSOS Signing Certificates expire when the associated DEA Registration expires.
 - For a more detailed explanation of identifying certificates, see "Identifying CSOS Certificates."

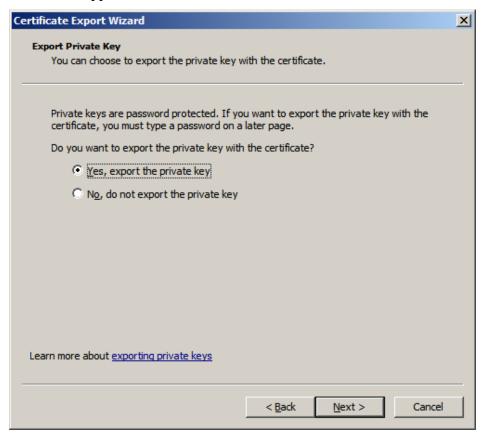


Please note: The certificate names used in this example will vary from what appears on your computer.

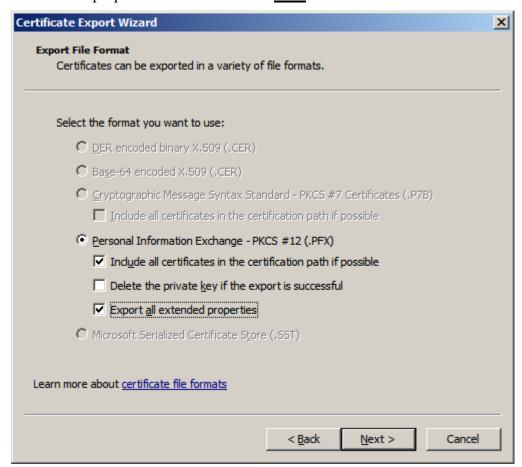
5. At the *Certificate Export Wizard* screen, click **Next**.



- 6. Verify that "Yes, export the private key" is selected and click Next.
- if the "Yes, export the private key" option is not available, please contact DEA E-Commerce Support.



7. Select "Include all certificates in the certificate path if possible" and *only* "Export all extended properties..." then click the <u>Next</u> button.

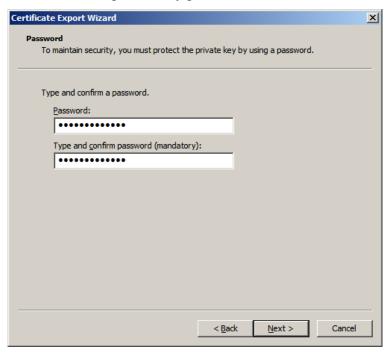


Notes:

- Including all certificates in the certificate path will store the E-Commerce Root and CSOS Sub CA certificates (if found in this certificate store) with the exported PFX certificate file.
- Deleting the private key will render useless the certificate in the certificate store. If the PFX is lost, corrupted, or incorrectly exported, there will be not original certificate (with private key) to work off of.

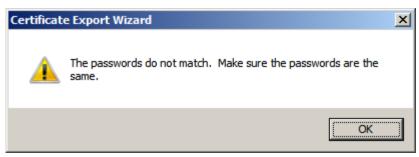
8. Type and confirm a backup password for the certificate.

This step allows for a backup password to be **created** for protection of the exported certificate file (PFX file). The owner of the certificate must enter this password and be the only person to know it. The password created may be the same as the certificate's private key password, which was created during retrieval.

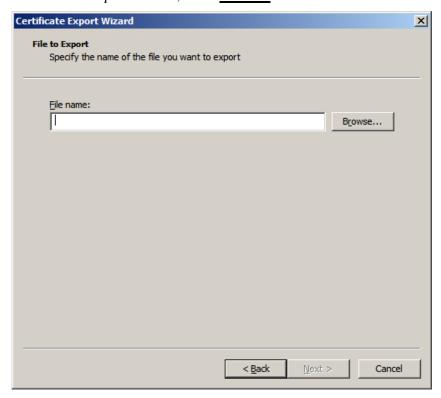


Only the owner of the certificate may enter and have knowledge of this password.

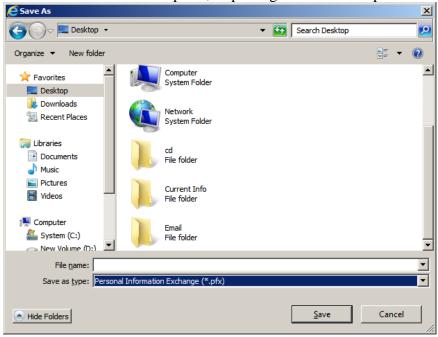
The following error will be received if the typed *Confirm password* text does not match the password:



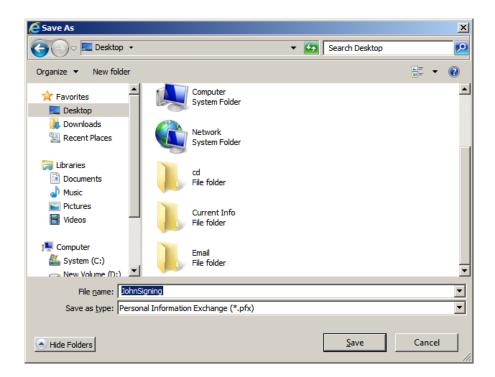
9. At the File to Export screen, click **Browse**.



- 10. Select a location to export the file to.
 - To save the file to the desktop, switch the 'Save in' drop down list to **Desktop**.
 - The certificate may be exported to a different location, but if transferring the certificate to another computer, exporting to the Desktop first is recommended.

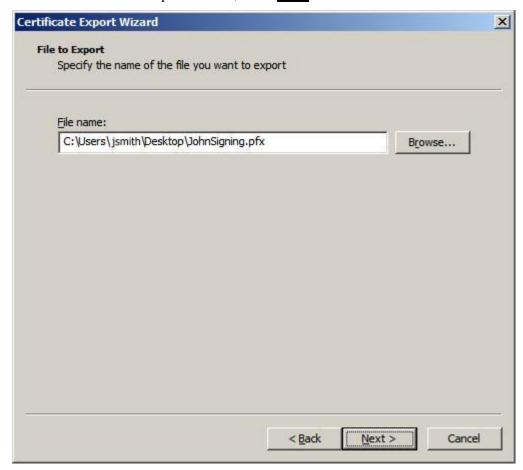


- 11. Enter a name for the Certificate file in the 'File name:' field and click <u>Save</u>. Naming the certificate is *very* important for identification purposes since the data in the certificate will not be visible when the certificate is in the form of a PFX file. For this reason, certificates with vague names are difficult to manage.
 - Signing Certificates should be named using one of the following naming conventions:
 - o CSOSOrdering or JohnOrdering
 - o CSOSSigning or JohnSigning
 - o John_AB1234567 (please use when the subscriber has multiple certificates for multiple DEA Registration numbers)
 - Administrative Certificates should be named using one of the following naming conventions:
 - o CSOSAdmin or JohnAdmin



12. Verify that the 'Save as type' option is set to "Personal Information Exchange (*.pfx)". Click **Save**.

13. Back at the *File to Export* screen, click **Next**.



- 14. At the Completing the Certificate Export Wizard screen, click Finish
- 15. The *Exporting your private exchange key!* Screen will vary depending on whether the certificate has a password or not. If there is no password on the certificate, simply click \underline{OK} . If there is a password, you will be required to enter it here before clicking \underline{OK} .

- **Do not select the** *Remember password* option check box.
- Only the owner of the certificate is authorized to enter and have knowledge of this password.
- This password is cAsE sEnSiTiVe. If unable to remember this password, please attempt all passwords that are typically used by the subscriber. Contact DEA Diversion E-Commerce Support if unable to export.



16. At the *The export was successful* screen, click **OK**.



If an error received, then the private key password was not entered correctly. Remember, this password is case sensitive and was set during initial retrieval.

4.3 Certificate Verification Steps

Once the certificate is downloaded, the Subscriber data in the certificate may be verified for accuracy. Verification may be done using available commercial PKI ordering system software applications. Contact the DEA Diversion E-Commerce Support if you require assistance.

The certificate extensions described in this document are defined in the DEA certificate profile. The DEA certificate profile can be obtained from the DEA Diversion E-Commerce Website at http://www.DEAecom.gov/pki cert crl.pdf.

The following six extensions have been added to a standard X.509 certificate to support DEA business requirements. CSOS Signing Certificates contain data for each of these six extensions, while CSOS Administrative Certificates do not contain any information associated with a DEA Registration.

- **DEA Certificate Version Number Information** This extension is to provide version control and identification for any future technology advancements.
- **DEA Registrant Name** Identifies the name of the DEA registrant associated with the certificate.
- **DEA Valid Schedules** Identifies the DEA controlled substance schedules that the holder of the certificate is authorized to handle.
- **DEA Business Activity** Identifies the DEA business activity of the associated DEA registration.
- **DEA postal Address** Identifies the place of business that is registered with the DEA for the respective DEA registration number identified in the DEA registration number extension.
- Hashed DEA Registration Number— SHA-1 Identifies the hashed DEA number associated with the certificate.

To interpret DEA extensions the following steps should be followed:

- View/Open the certificate
- View the DEA schedule extension in the certificate
- Decode the value of the DEA schedule extension

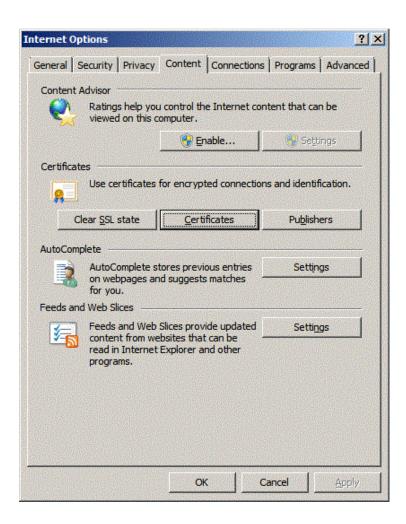
4.3.1 View/Open the certificate

A CSOS Certificate must be opened in order to view the data it contains about its owner and associated DEA Registration.

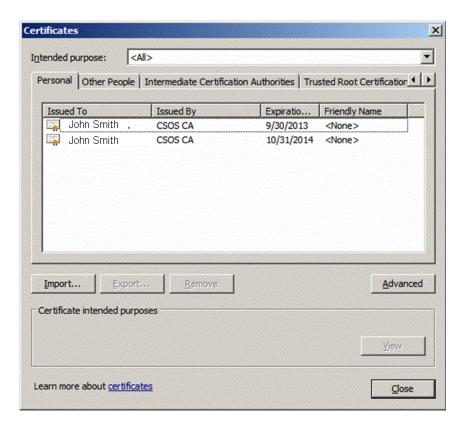
- 1. Open Internet Explorer on the computer used to retrieve the certificate, or the computer that the certificate is currently installed on.
- 2. Open the Tools menu and select **Internet Options**.



3. Select the Content tab and click the **Certificates** button.



- 4. If installed on this computer in Internet Explorer, the CSOS Certificate(s) should be available in this Certificates list on the Personal tab.
 - All CSOS Certificates are issued by "CSOS CA."
 - CSOS Administrative Certificates expire three (3) years for their data of issuance.
 - CSOS Signing Certificates expire when the associated DEA Registration expires.



- 5. Double click on the Certificate to be verified.
- 6. Click on the **<u>Details</u>** tab to view the Certificate's DEA extensions.



4.3.2 View the DEA extension in the certificate

Each extension or Field in the certificate is shown in the left column of the Certificate's details tab. The Certificate's associated value for that field is displayed in the Value column as well as the bottom pane when a field is selected. The below table should be used to interpret the Field ("object identifier") number to a readable DEA extension name. This section of the Subscriber Manual documents how to interpret and verify the data contained in a CSOS Certificate.

Certificate Field Value	DEA Extension Name
(object identifier)	
2.16.840.1.101.3.5.1	DEA Certificate Version Number
2.16.840.1.101.3.5. 2	DEA Registrant Name
2.16.840.1.101.3.5.4	DEA Schedules
2.16.840.1.101.3.5. 5	DEA Business Activity
2.16.840.1.101.3.5. 6	DEA Registered Postal Address
2.16.840.1.101.3.5.7	Hashed DEA Registration Number (SHA-1)

Figure 1. Certificate Field Value Mapping to DEA Extension Name

4.3.3 DEA Certificate Version Number Information

The DEA Certificate Version Number Information extension allows relying party applications to identify the DEA profile version being used by the particular certificate. This enables multiple profile versions to be used at the same time without ambiguity.

The value of the extension is displayed as a hexadecimal value. The DEA Certificate Version Number Information value is the last two characters (i.e. 00) of the extension value. The current value is fixed at 0 to represent version 1 of the DEA certificate profile.

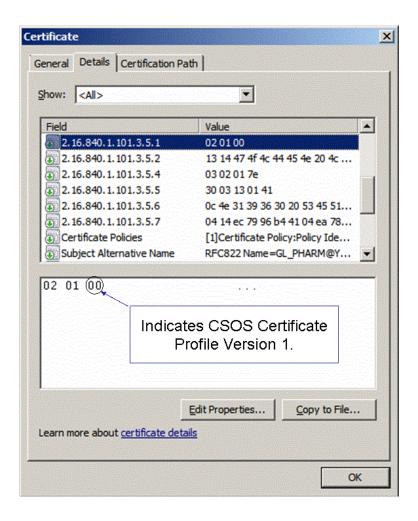


Figure 2. DEA Certificate profile version

In the above figure, the DEA certificate profile version extension value is 00, which is Version 1.

4.3.4 DEA Registrant Name

The DEA Registrant Name extension is used to identify the DEA Registrant for which a CSOS Signing Certificate is associated. Example: *last name, first name middle initial* (Doe, John A) or *business name* (Acme, Inc.).

Highlight section 2.16.840.1.101.3.5.2 to view the associated Registrant Name, as displayed below in Figure 3.

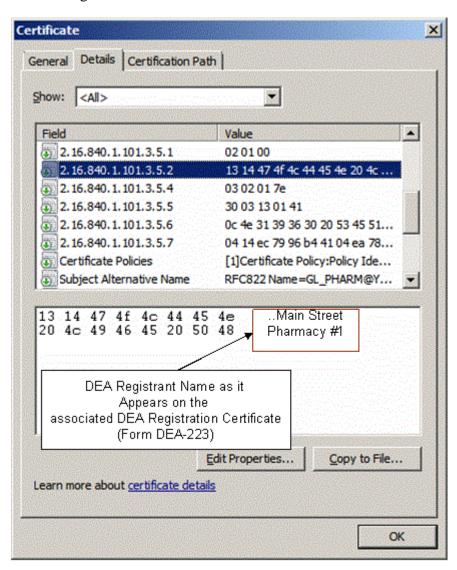


Figure 3. DEA Registration Name

In the above figure, the DEA registration name is Sample CheatSheet.

4.3.5 DEA Schedules

The *DEA Schedules* extension reflects the controlled substance schedules the certificate owner is authorized to prescribe or dispense.

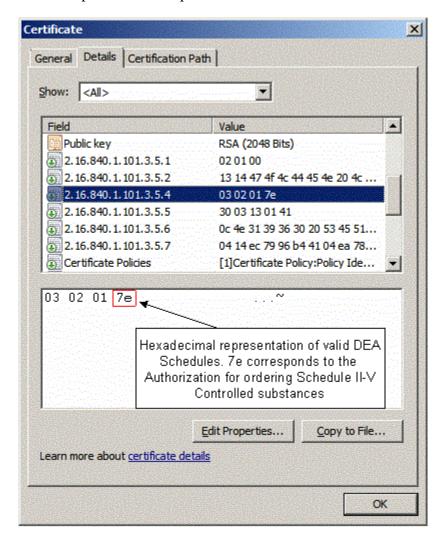


Figure 4. DEA Schedule Extension

In the above figure, the DEA schedule extension value is 7E. '7E' represents a hexadecimal number (Base-16 rather than the standard base-10 counting system). When translated to binary (Base-2), the allowable ordering schedules can be determined. Since the majority of CSOS Signing Certificates are issued for schedules II-V (2, 2N, 3, 3N, 4, and 5), this translation will not be necessary if your Certificate's associated DEA Registration number is authorized for these schedules.

4.3.5.1 Convert a Hexadecimal to Binary

Use the last two characters of the Certificate Extension Value as shown in Figure 4. Using each of the two characters separately, the following conversion table allows the associated binary value to be determined.

Hex Value	Bii	nary	Val	ue
0	0	0	0	0
1	0	0	0	1
2	0	0	1	0
3	0	0	1	1
4	0	1	0	0
5	0	1	0	1
6	0	1	1	0
7	0	1	1	1
8	1	0	0	0
9	1	0	0	1
Α	1	0	1	0
В	1	0	1	1
С	1	1	0	0
D	1	1	0	1
Е	1	1	1	0
F	1	1	1	1

Figure 5. Hex to binary conversion table

Using the above conversion table for an extension value of '7E':

- Hexadecimal value of 7 translates to the binary 0111.
- Hexadecimal value E translates to binary 1110.
- Combining the two binary values results in **01111110**.

The resulting binary number (i.e. 01111110) can be used to determine the authorized ordering Schedules. Each 0 or 1, called a 'bit', represents a DEA Schedule. Reading from left to right, each bit has a position (position 0 through 7), which maps to a DEA Schedule as documented in Figure 6.

- A 0 bit indicates an unauthorized schedule.
- A 1 bit indicates an authorized schedule.

The table below provides a mapping of allowable schedules to bits in the DEA schedule extension.

Bit	Schedule	
0	Schedule I Narcotic and Non-narcotic	1
1	Schedule II Narcotic	2
2	Schedule II Non-narcotic	2n
3	Schedule III Narcotic	3
4	Schedule III Non-narcotic	3n
5	Schedule IV	4
6	Schedule V	5
7	Unused	N/A

Figure 6. Controlled Substance Schedule Bit

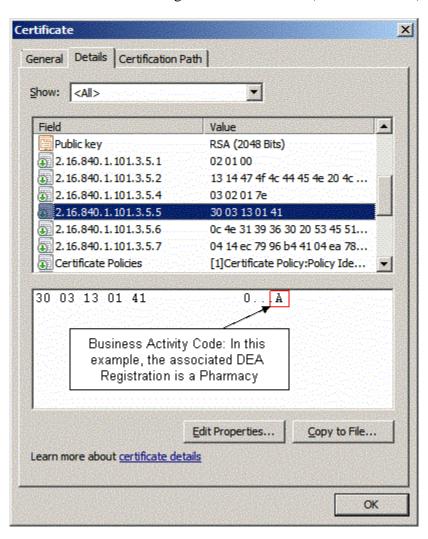
The table below displays sample schedule to bit to hex value mappings.

Bit field	0	1	2	3	4	5	6	7		
Schedules	1	2	2n	3	3n	4	5	Unused	Decimal	HEX
	_		211	-				Unuseu		
2,2n,3,3n,4,5	0	1	1	1	1	1	1	0	126	7 E
2, 3,3n,4,5	0	1	0	1	1	1	1	0	94	5 E
2n,3,3n,4,5	0	0	1	1	1	1	1	0	62	3 E
2	0	1	0	0	0	0	0	0	64	4 0
2n	0	0	1	0	0	0	0	0	32	20
3n 4 5	0	0	0	0	1	1	1	0	14	0 E
2n 3n 4 5	0	0	1	0	1	1	1	0	46	2 E

Figure 7. DEA extension value conversion table

4.3.6 DEA Business Activity

The *DEA Business Activity* extension identifies the business classification of the CSOS Subscriber's associated DEA Registration. The DEA Business Activity code must be consistent with the associated DEA Registration Certificate (Form DEA-223).



Business Activity	Code
Pharmacy	Α
Hospital/Clinic	В
Practitioner	С
Teaching Institution	D
Manufacturer	Е
Distributor	F
Researcher	G
Analytical Lab	Н
Exporter	K
Mid-Level Practitioner	М
Narcotic Treatment Programs	
Maintenance	Ν
Detoxification	Р
Maintenance & Detoxification	R
Compounder/Maintenance	S
Compounder/Detoxification	T
Compounder/Maint. & Detox	U

Table 1: DEA Business Activity Codes

4.3.7 DEA Postal Address

The *DEA postal address* Certificate extension identifies associated DEA Registration's postal address as it is registered with DEA.

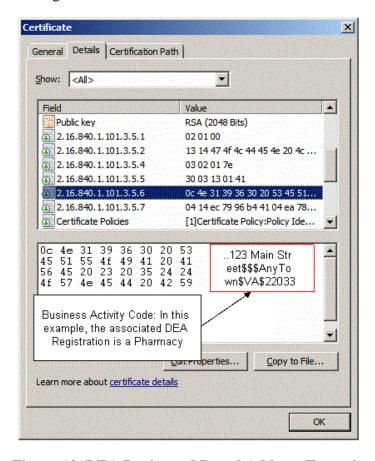


Figure 10. DEA Registered Postal Address Extension

The resulting extension value takes the format of: Address 1\$Address 2\$Address 3\$City\$State\$Zip Code as documented in Figure 11.

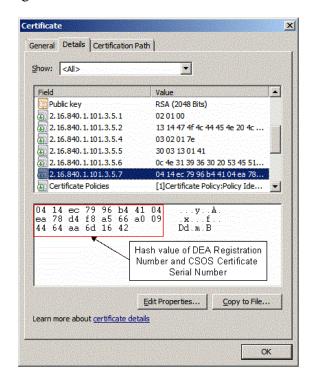
CSA Database Field	CSA Database value
Example 1	
Address 1	Dept 1
Address 2	123 Main Street
Address 3	PO Box 45678
City	Home Town
State	MD
Zip Code	12345-6789
Extension Value	Dept 1\$123 Main Street\$PO Box 45678\$Home Town\$MD\$12345-6789
Example 2	
Address 1	123 Main Street
Address 2	
Address 3	

City	Home Town
State	MD
Zip Code	12345-6789
Extension Value	123 Main Street \$\$\$Home Town\$MD\$12345-6789

Figure 11. DEA Postal Address Example Values

4.3.8 DEA Registration Number

For privacy reasons, a CSOS Signing Certificate's associated DEA Registration number does not appear in clear text in the Certificate. The DEA Registration number, along with the Certificate Serial Number, are hashed together and included in the Certificate Field 2.16.840.1.101.3.5.7. Using a hash (an irreversible encoding), the DEA Registration number may be verified only if it is already known. Since the purchaser's DEA Registration number is included in all CSOS transactions, the supplier may use the given Registration Number from the order along with the Certificate's Serial Number to determine the validity of the DEA Registration Number in the Certificate used to digitally sign the order.



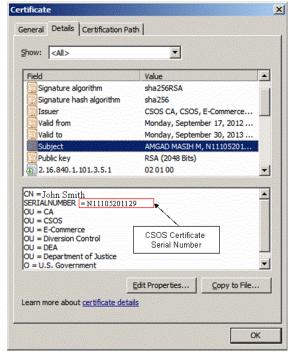


Figure 12. Hashed DEA Registration Number Extension

Figure 13. CSOS Certificate Serial Number

SHA-1 Hash Value Using	
DEA Registration Number	AA1234567
CSOS Certificate Serial Number	X010122006004
Concatenated DEA Registration Number and CSOS Certificate Serial Number	AA1234567X010122006004
SHA-1 Hash value result using the above concatenated numbers (this is the value appearing in the Certificate)	c6d8 9a70 3df7 cf8b bda9 4a2f 37bb c6a4 3029 2578

Figure 14. Hashed DEA Registration Number Value

Figure 14 provides an example for the inputs and output of the hash value placed in a CSOS Signing Certificate. A Subscriber may verify a Certificate's hash value using software such as a hashing calculator utility. An invalid hash value will result in an error when a supplier attempts to validate a purchase order. Please contact DEA Diversion E-Commerce Support if such an error occurs.

5 Certificate Management

5.1 Certificate Renewal

Certificate Renewal is the process of DEA issuing a *new* certificate to a subscriber. The subscriber will be issued new activation codes and must retrieve the new certificate via DEA's secure certificate retrieval Website.

All CSOS digital certificates have an expiration date after which the certificate will no longer be valid for electronic ordering or digitally signing communications.

• CSOS Signing Certificates expire when the associated DEA Registration expires.

Signing Certificates must be renewed in addition to the DEA Registration.

• CSOS Administrative Certificates expire three years from the date of issuance.

The CSOS RA sends an E-mail notifying the Subscriber and the Subscriber's CSOS Coordinator 45 days prior to the expiration date of the Subscriber's CSOS certificate. The Coordinator is responsible for renewing the certificate and is provided Certificate renewal instructions with the E-mail notice. Failure to renew a CSOS Signing Certificate will result in an inability to sign electronic orders for controlled substances.

There are two types of renewal methods for CSOS Certificates.

- Electronic renewal may be used twice certificates may be renewed via E-mail or over the phone up to two times after initially enrolling in CSOS.
 - o **E-mail**: E-mails must be digitally signed. If not digitally signed, DEA will call to validate the Coordinator's identity.
 - o **Phone**: the Coordinator may call DEA E-Commerce Support. Certificates will be renewed once DEA has validated the Coordinator's identity.
- Initial enrollment must be used the third time Subscribers are required to reestablish identity using the initial registration process (mailing in a new application package) as discussed in Sections 2 and 3 of this Subscriber Manual.

5.2 Certificate Revocation

Certificate revocation results in the loss of ability of the digital certificate holder to use the certificate for electronic ordering purposes by placing the certificate information onto a "Certificate Revocation List", or CRL. Suppliers are required to check each digitally signed order to ensure that the certificate associated with the digital signature has not expired or been revoked. Revoked certificates appear on a CRL within 24 hours of acknowledgement by DEA Diversion E-Commerce Support, or within six (6) hours of if the revocation reason is due to known or suspected compromise of the private key.

5.2.1 Revocation Reasons

A Subscriber's certificate may/will be revoked under the following circumstances:

- The subscriber (certificate holder) no longer orders controlled substances and/or is no longer employed by the organization associated with the Certificate's DEA Registration number
- Subscriber information contained in the certificate has changed including legal name changes and E-mail address changes
- DEA Registration (as indicated on the paper DEA Registration Certificate, form DEA-223) information has changed including DEA Registration name, number, address, or authorized ordering schedules are reduced
- DEA posts notice that certificate holder's DEA Registration has been revoked, suspended or restricted, that the Registration information has changed, or that the Registration has been terminated
- It can be demonstrated that the Subscriber has violated the stipulations of the Subscriber Agreement
- The private key is lost, compromise is suspected, or cannot be accessed for any reason (the private key used when digitally signing a document is activated by a password or token under the Subscriber's sole control, so it is important not to divulge this information to anyone, even your Registrant or CSOS Coordinator)
- The Subscriber, the DEA Registrant under whose Registration a certificate holder obtained a certificate, or CSOS Coordinator requests that the affiliated Subscriber certificate be revoked

Official policy regarding Certificate revocations may be found in the E-Commerce Certificate Policy available on www.DEAecom.gov.

5.2.2 Procedure for Revocation Requests

The DEA E-Commerce Website contains detailed instructions that may be used to request certificate revocation. Revocation requests can be made by sending a digitally signed email to CSOSrevocation@DEAecom.gov or by telephone to 1-877-DEA-ECOM (1-877-332-3266).

In the event of suspected compromise, the Subscriber, or other authorized person, can request revocation via a telephone call to DEA Diversion E-Commerce Support at 1-877-DEA-ECOM (1-877-332-3266). Telephone requests for revocation will be authenticated. **Revoked or suspended certificates must not be used to digitally sign orders for controlled substances!**

6 Certificate Security

The following Certificate Security section refers frequently to the Subscriber's private key. The private key is the component of the subscriber's digital certificate used for digital signatures andtherefore is not accessed by anyone (including DEA and suppliers) other than the subscriber.

Passwords or security tokens used to activate the Subscriber private key must never be shared. Methods for protecting the private key and the activation data to that key are discussed in this Certificate Security section. All CSOS Subscribers (i.e. certificate holders) must provide secure storage for their private key. The following sections outline some basic guidelines that help to mitigate the likelihood of a private key compromise

Please note that the Code of Federal Regulations and DEA Diversion Control E-Commerce System Certificate Policy govern the CSOS program. Additionally, the CSOS Subscriber Agreement and Privacy Policy bind all CSOS subscribers. These documents are the official sources for policy regarding the topics mentioned in this section.

6.1 Private keys must be kept private.

If someone other than the Subscriber (owner of the certificate) has access to the private key or password, regulations require that the Subscriber immediately report the compromise (or suspected compromise) to DEA Diversion E-Commerce Support so that the certificate can be revoked. It may be possible for a new certificate to be issued.

6.2 Secure access to the private key.

Use strong passwords or multi-factor authentication to secure access to the private key. The process of digitally signing an order will require the Subscriber to either input a password known only to him or her, or to use a biometrically-activated token (proving that the Subscriber is the private key owner). Passwords used to secure access to the private key must be strong enough so that they cannot be guessed or easily "cracked." Strong passwords include the following characteristics:

- At least 8 characters
- Upper and lower case characters
- \bullet Numbers and/or special characters, such as the * or # in the middle of the password
- Names or words that *cannot* be found in the dictionary

6.3 Enable the Workstation/PC Inactivity Timeout for 10 minutes.

Once the Subscriber private key has been activated to digitally sign orders, the key must not be left unattended or otherwise available to unauthorized access. Windows PCs using a password-protected screen saver that activates after 10 minutes of inactivity help

prevent such unauthorized access if you are away from your desk. Contact your network administrator or DEA Diversion E-Commerce Support for information on this if you are using a Windows PC.

6.4 Anti-Virus/Spyware Software

Using up-to-date anti-virus/spy ware software helps prevent Trojan horse programs and malicious spy ware, which may "stealthily" install a keyboard logger capable of recording the password and other private information entered into the system. This information can then be transmitted without your knowledge to other parties.

6.5 Backing-up or Escrowing the Private Key

Private Key escrowing involves allowing a third party to maintain a copy of the private key (i.e. the CSOS Certificate). Regulations and policy explicitly prohibit escrowing or backing up of a private key used for digital signatures.

6.6 Method of Deactivating Private Key

After use, the Subscriber must deactivate the key (e.g., via a manual logout procedure, or automatically after a period of inactivity) so that someone following the Subscriber cannot sign using the key. It is important to completely close (not minimize) the browser window if using a Web-ordering environment to ensure that the activation information is not accessible to others.

6.7 CSOS Application and Auditing Information

DEA does not provide a CSOS software application to organizations for electronic ordering. DEA provides digital certificates for use with approved CSOS enabled software applications. Organizations must develop or purchase CSOS applications that have been audited to DEA regulations by a third party (independent) auditor of the organization's choosing to ensure that all of the regulations governing the use the electronic orders have been met in the software application. DEA Diversion Investigators may ask an organization to provide evidence of this audit information at any time, and may internally audit an organization's local enrollment (application) processes to ensure that the processes are maintained as specified in the DEA Diversion Control E-Commerce System Certificate Policy available at www.DEAecom.gov. If you have questions about this auditing or the availability of commercial CSOS applications, please contact DEA Diversion E-Commerce Support. For more information on Auditing, please see Section 7 of this Subscriber Manual or the Code of Federal Regulations available on www.DEAecom.gov.

7 CSOS Software Application Audit Requirements

Software applications purchased or developed internally for use with CSOS digital certificates for the purposes of electronically ordering controlled substances must comply with the technical requirements discussed in the 21 CFR, Parts 1305 and 1311. To ensure that the digital signature system functions properly for both the supplier and purchaser, DEA requires that the

9 Glossary

Access Code	One of two pieces of information required for retrieving a CSOS Certificate. The Access Code is a number provided to the CSOS subscriber via E-mail.
Access Code Password	One of two pieces of information required for retrieving a CSOS Certificate. The Access Code password is a combination of numbers and letters and is provided to the CSOS Subscriber's Coordinator via postal mail.
Activation	See Certificate Retrieval.
Activation Notice	A communication (E-mail and postal mailed document) from DEA containing information required to retrieve a CSOS Certificate.
Addendum	A CSOS Application Form attachment (Form DEA-254) allowing a CSOS Applicant to list additional DEA Registration Numbers that he/she is requesting to be associated with for the CSOS Program.
Applicant	See CSOS Applicant
Application Package	See Certificate Application Package
Authenticate	To confirm the identity of an entity when that identity is presented.
Authentication	Security measure designed to establish the validity of a transmission, message, or originator, or a means of verifying an individual's authorization to receive specific categories of information.
Backup	Copy of files and programs made to facilitate recovery if necessary.
Certificate	(Subscriber) certificates identify the individual named in the certificate, bind that person to a particular public/private key pair, and provide sufficient information demonstrating the Subscriber is operating under the authority of the DEA Diversion Control E-Commerce System program.
Certificate Application	General term for form DEA-251, DEA-252, and DEA-253. A CSOS Certificate Application is the form submitted by an individual requesting enrollment in the CSOS Program.
Certificate Application Package	A term used for any CSOS Certificate Application with all required supporting documentation.

Certificate Policy (CP)	An official policy document governing the CSOS Program. The DEA Diversion Control E-Commerce System Certificate Policy specifies: 1. The Certification Authorities, the Subscribers, and the Relying Parties authorized to participate in the PKI program described by this Policy, 2. The obligations of the participants governed by this Certificate Policy, and 3. The minimum requirements for the issuance and management of digital certificates used within the CSOS programs - and other suitableapplications.
Certificate Renewal	The process of acquiring a new CSOS Certificate once a current CSOS Certificate has been revoked or has expired.
Certificate Retrieval	The required process of generating a CSOS Certificate via DEA's secure Website.
Certificate Revocation	The processed of invalidating a CSOS Certificate prior to its expiration date.
Certificate Revocation List (CRL)	A list maintained by a Certification Authority of the certificates that have been revoked prior to their stated expiration date.
Certificate Store	The component of an Internet browser (such as Internet Explorer or Firefox) that provides access to digital certificates. Certificates may be viewed or managed from within a browser's certificate store.
Certification Authority (CA)	This term is used to identify both the Root CA role operated by DEA as well as the Subordinate CA that would be operated by other entities in compliance with DEA regulations.
Compromise	Disclosure of information to unauthorized persons, or a violation of the security policy of a system in which unauthorized intentional or unintentional disclosure, modification, destruction, or loss of an object may have occurred.
CSOS Applicant	An individual requesting enrollment in the CSOS Program who has not yet been approved and issued a CSOS Certificate. Applicant's include Registrants, Coordinators, and Power of Attorneys.
CSOS Coordinator	An individual delegated and authorized by a DEA Registrant to be the administrator for associated DEA Registration numbers.
CSOS Power of Attorney (POA)	A non-administrative individual enrolling or enrolled in the CSOS Program for signing electronic orders for controlled substances. A POA applicant can be any individual who has been granted ordering Power of Attorney by a Registrant and has been approved by a CSOS Coordinator.
CSOS Subscriber	An individual enrolled in the CSOS Program who has been issued a CSOS Certificate by DEA.

Digital Cianatara	The use of a digital cortificate's private leave to "cien" a digital
Digital Signature	The use of a digital certificate's private key to "sign" a digital communication. For electronic ordering of controlled substances, each order must be digitally signed using a CSOS certificate for
	authentication, order integrity, validation, and non-repudiation (inability to deny placing an order) purposes.
Drug Enforcement	The DEA regulates the manufacture and distribution of controlled
Administration	substances in the United States.
(DEA)	
Enrollment	The process of applying with DEA in order to participate in the CSOS Program.
Hash	A hash value, or message digest, is a unique number generated
	from a string of text. Since changing any character in the text
	string results in a new hash value, hash values are used to provide data integrity.
Key Escrow	A deposit of the private key of a Subscriber and other pertinent
	information pursuant to an escrow agreement or similar contract
	binding upon the Subscriber, the terms of which require one or
	more agents to hold the Subscriber's private key for the benefit of
	the Subscriber, an employer, or other party, upon provisions set
Key Pair	forth in the agreement. Two mathematically related keys having the properties that:
Key Fair	Two mathematicany related keys having the properties that.
	1. One key can be used to encrypt a message that can only be
	decrypted using the other key, and
	2. Even knowing one key, it is computationally infeasible to
	discover the other key.
Local Registration	The role of CSOS Coordinator subscribers in verifying the identity
Authority (LRA)	and authority of each CSOS Power of Attorney applicant enrolling in the CSOS Program.
Object	An alphanumeric number registered with an internationally
Identifier(OID)	recognized standards organization used within PKI to uniquely
	identify policies and supported cryptographic algorithms.
Power of Attorney	A formal letter where a Registrant grants an individual the
Letter	authority to sign controlled substance orders for the indicated DEA Registration number.
Private Key	The part of a digital certificate known only by the owner:
	(1) The key of a signature key pair used to create a digital
	signature. (2) The key of an encryption key pair that is used to
	decrypt confidential information. In both cases, this key must be
D-LE-T	kept secret.
Public Key	The part of a digital certificate that is publicly known: (1) The key of a signature key pair used to validate a digital
	signature. (2) The key of an encryption key pair that is used to
	encrypt confidential information. In both cases, this key is made
	publicly available normally in the form of a digital certificate.
Public Key	A set of policies, processes, server platforms, software and
Infrastructure	workstations used for the purpose of administering certificates and
(PKI)	public-private key pairs, including the ability to issue, maintain,
	and revoke public key certificates.

Registrant	The individual who signed, or is authorized to sign, the most recent application for DEA Registration renewal. The Registrant is
	typically and owner or officer for the organization.
Registration Authority (RA)	The unit within DEA's CSOS Certification Authority responsible for CSOS Subscriber Enrollment. The CSOS RA processes CSOS Subscriber Application packages and adjudicates the identity and validity of all CSOS Applicants.
Relying Party	A Relying Party is the entity that, by using a Subscriber's certificate to verify the integrity of a digitally signed message, identifies the creator of a message, and relies on the validity of the public key bound to the Subscriber's name. The Relying Party is responsible for checking the validity of the certificate by checking the appropriate certificate status information. The Relying Party must use the certificate to verify the integrity of a digitally signed message and to identify the creator of a transaction.
Renewal	See Certificate Renewal.
Retrieval	See Certificate Retrieval.
Root CA	The DEA Diversion Control E-Commerce System Root CA shall operate in accordance with the provisions of its Certification Practices Statement. The DEA Diversion Control E-Commerce System Root CA shall also perform the following functions: (1) accept and process applications for operations from Subordinate CAs; (2) issue certificates to Subordinate Certificate Authorities approved by the PMA; (3) publish Subordinate CA certificate status information.
Subordinate CA	A Subordinate CA is an entity authorized by the PMA to create, sign, and issue public key certificates to authorized CSOS Subscribers.
Subscriber	See CSOS Subscriber.