Government Healthcare Services Office
Texas PBM

CONDUENT

Texas Vendor Drug Program

Texas Drug Code Index Electronic Certification of Information (eCOI)

Agent User Guide

April 19, 2021
Version 3.5

Revision History

Version	Date	Description	Author
1.0	10/21/2020	DRAFT eCOI Instructions	B Stevens
2.0	01/04/2021	Updated with new functionality	B Stevens
3.0	01/31/2021	Denial Reasons	B Stevens
3.1	01/31/2021	Email Examples	B. Stevens
3.2	02/03/2021	Wording changes	B. Stevens
3.3	02/25/2021	Added new permissions, HHSC attachment information	B. Stevens
3.4	03/08/2021	Updated wording	B. Stevens
3.5	04/19/2021	Added new screen shots for country field and other APR115 changes	B. Stevens

Contents

1 Purpose

The Texas Health and Human Service Commission (HHSC) requires drug companies to complete the Certificate of Information (COI) for the Vendor Drug Program (VDP) to consider drugs for coverage on the formulary in accordance with 1 TAC Section 1921 (Addition of Drugs to the Texas Drug Code Index). The COI is used when a drug is new to the market or when an existing drug on the Texas Drug Code Index (TDCI), or formulary, has a new formulation or labeler changes. The TDCI is available online at www.txvendordrug.com/formulary.

On Feb. 1, 2021, VDP introduced the browser-based eCOI application to replace the paper COI form (HHS Form 1326). HHSC will no longer accept Form 1326 after March 31. VDP encourages drug manufacturers to contact **VDP-Formulary@hhsc.state.tx.us** to register for the eCOI portal

2 Procedure

A drug must have the following to be considered for inclusion on the TDCI:

1. A rebate agreement with the Centers for Medicare & Medicaid Services
2. A listing on the Medicaid Drug Rebate Program website
3. A listing on First Databank and Medi-Span

Drug companies with one or more of their products on the TDCI are responsible for using the eCOI portal to announce changes pertaining to any of the information on this online form no later than such revisions are scheduled to occur.

Drugs submitted through the portal should include the National Drug Code of the company who is holding the drug forth as its own and has the company's name on the label of the container sold to the pharmacy.

All drugs on the TDCI must bear the FDA-defined labeler code, except for a licensed, full-service drug wholesaler marketing the final sale to the provider.

3 Detailed Instructions

1. All fields in the "Drug Description", "Pricing Information", "Special Handling" and "Certification" sections should be completed in their entirety. The fields in the "Contacts" section should be completed as applicable.
2. The review process takes up to 90 days once the online form is submitted to HHSC and considered complete. The HHSC Drug Addition Process (PDF) explains the timeline of how drugs are added to the TDCI.
3. The form **must be accompanied** with FDA approval letter(s).
   Examples of FDA documents accepted:
   3.0. FDA new drug application approval letter

3.1. FDA abbreviated new drug application approval letter
3.2. FDA over-the-counter monograph
3.3. Other applicable documents

4. Drug companies must also submit the following:
   - Copy of package insert
   - Copy of non-expired Certificate of Liability Insurance
   - Material for physicians or file card, if available.
   - Other applicable documents

4 Supported Browsers

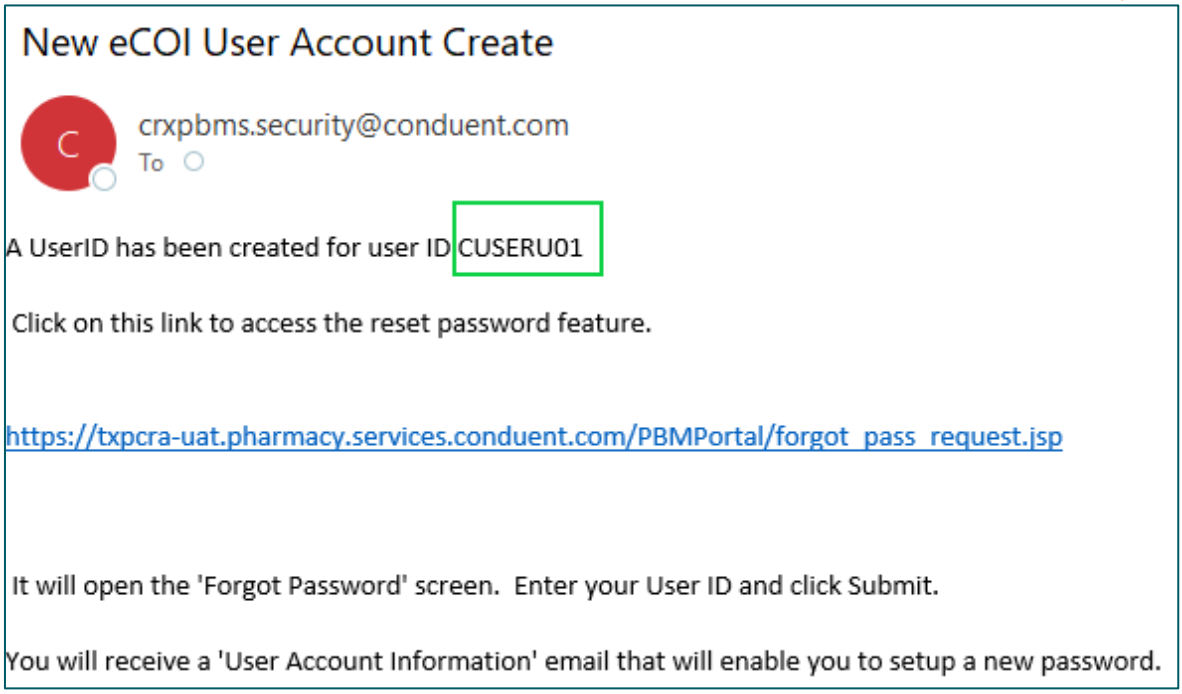
Browser	Version
Microsoft Internet Explorer	IE11 or above
Google Chrome	Supports latest stable browser version
Microsoft Edge	Not Supported
Firefox	Not Supported
Apple Safari	Not Supported

5 Certificate of Information Login

Before logging into the Certificate of Information Portal, the user must first register with HHSC and have obtained a username and password.

User is required to submit the Electronic Certificate of Information Portal Access (HHS Form 1403). Once approved, you will receive an email from crxpbms.security@conduent.com containing the user name

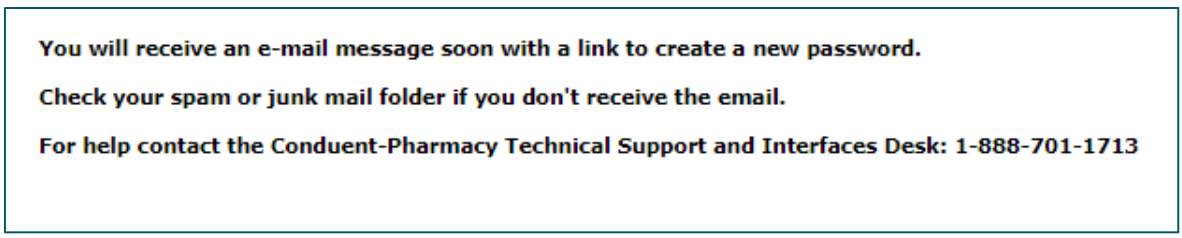
Example:



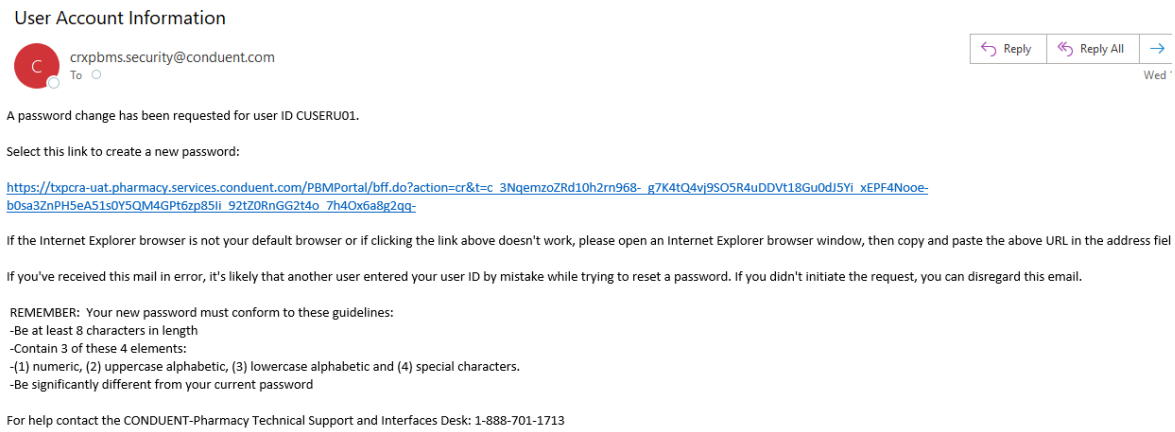
Click the link in the email and enter the USER ID from the email.

Click Submit

1. The USERID cannot be changed



User will receive another email to set/change the password



User Account Information

crxpbms.security@conduent.com
To

Reply | Reply All | →
Wed

A password change has been requested for user ID CUSERU01.

Select this link to create a new password:

https://txpcra-uat.pharmacy.services.conduent.com/PBMPortal/bff.do?action=cr&t=c_3NqemzoZRd10h2rn968-_g7K4tQ4vj9SO5R4uDDVt18Gu0dJ5Yi_xEPF4Nooe-b0sa3ZnPH5eA51s0Y5QM4GPt6zp85Ii_92tZ0RnGG2t4o_7h4Ox6a8g2qq-

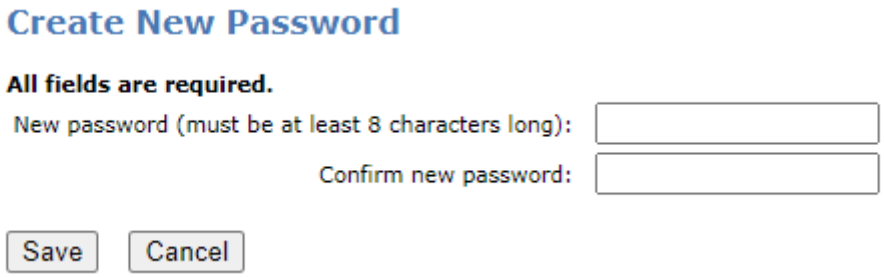
If the Internet Explorer browser is not your default browser or if clicking the link above doesn't work, please open an Internet Explorer browser window, then copy and paste the above URL in the address fiel

If you've received this mail in error, it's likely that another user entered your user ID by mistake while trying to reset a password. If you didn't initiate the request, you can disregard this email.

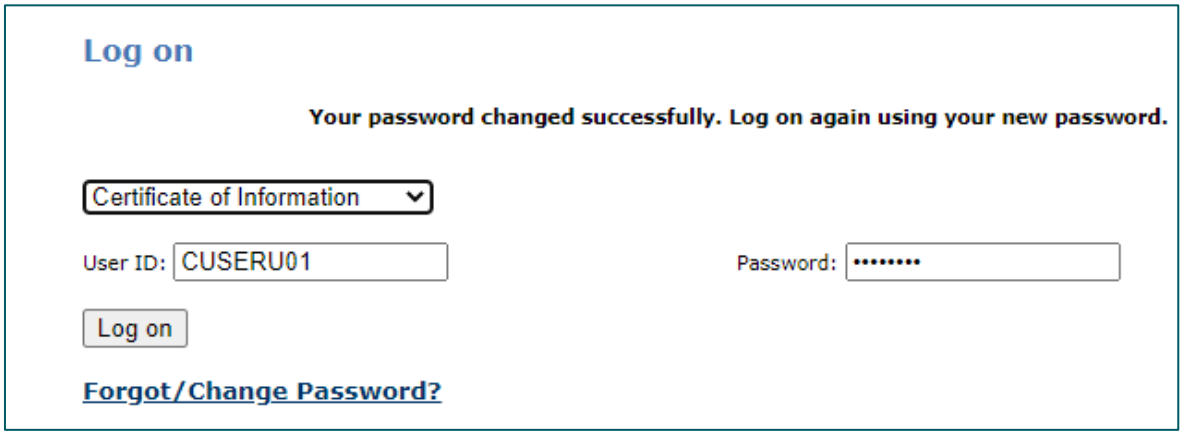
REMEMBER: Your new password must conform to these guidelines:
-Be at least 8 characters in length
-Contain 3 of these 4 elements:
-(1) numeric, (2) uppercase alphabetic, (3) lowercase alphabetic and (4) special characters.
-Be significantly different from your current password

For help contact the CONDUENT-Pharmacy Technical Support and Interfaces Desk: 1-888-701-1713

Click the link in the email

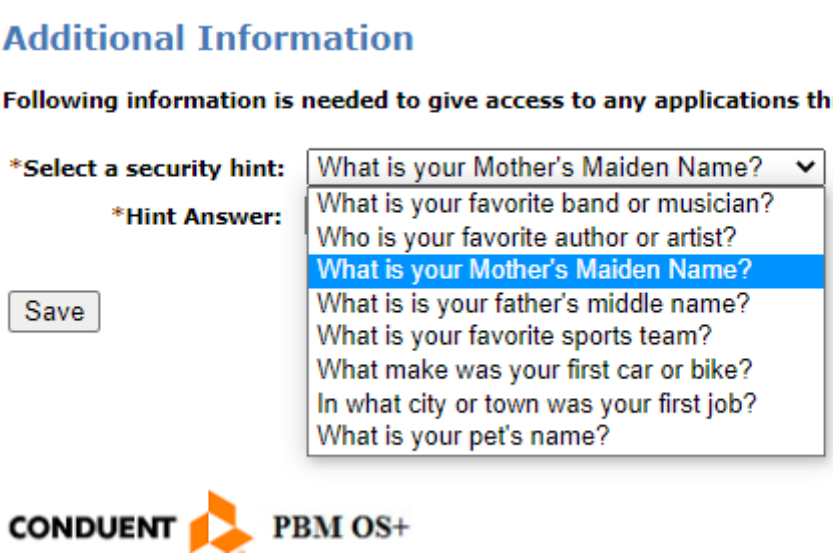


Log in using the USER ID and newly created password



Set the security hint question

Click Save



5.1 Permission Types:

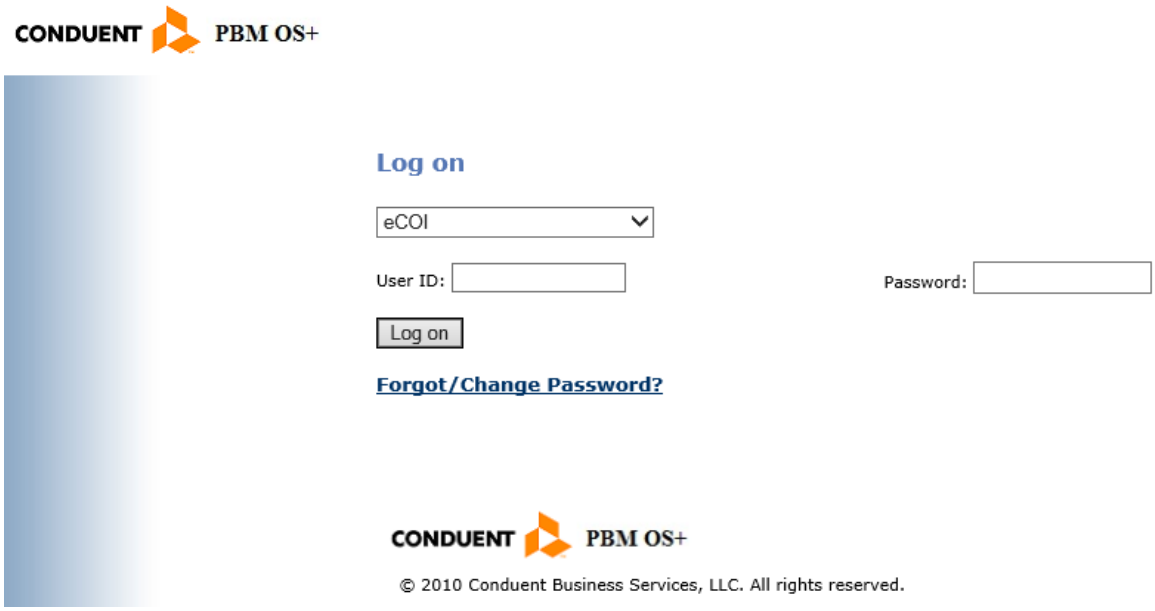
- Read-Only
  - Allows the user to update their contact information
  - Allows the user to view existing COIs created by other users within the same authorized label code(s)
- Update
  - Allows the user to update their contact information
  - Allows the user to view existing COIs created by other users within the same authorized label code(s)
  - Allows the user to create, edit, and submit a COI to HHSC for approval

6 Website Address

https://txpcra.pharmacy.services.conduent.com/PBMPortal/login.jsp

Use the above URL to access the Certificate of Information Portal

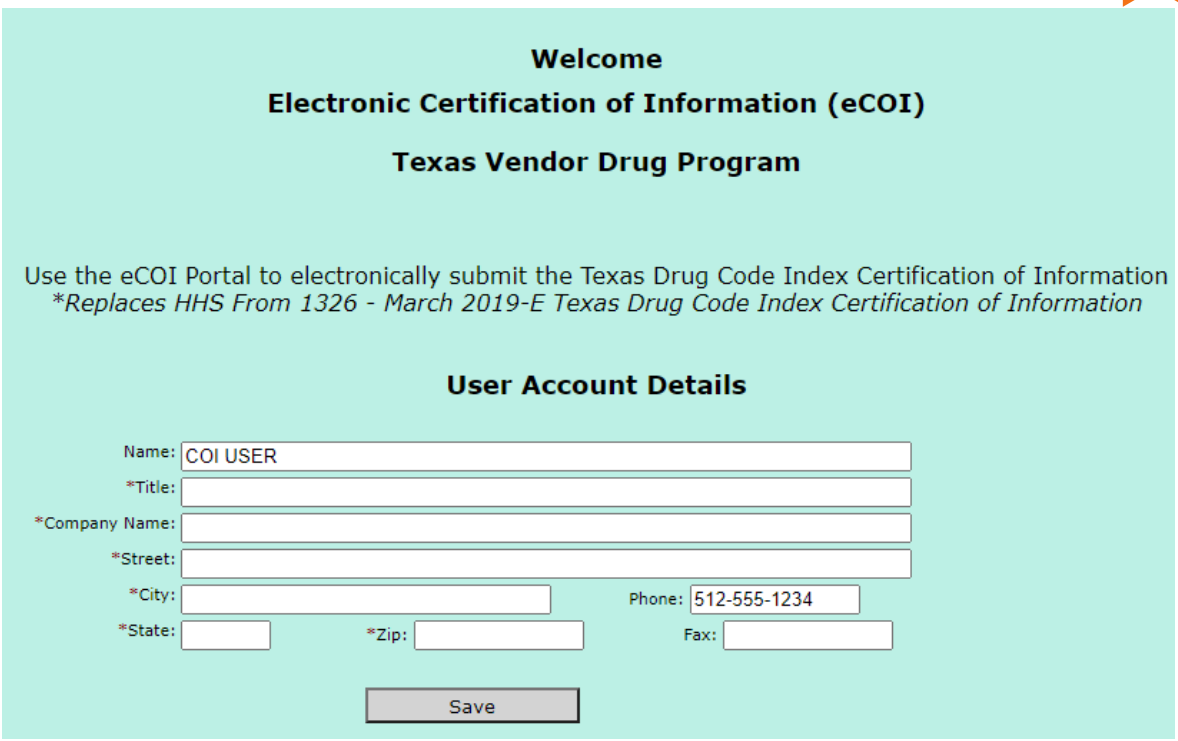
7 Portal Login Screen



1. Select "eCOI" portal from the drop-down list
   - Users do not have access to any other portals listed in the drop-down
2. Enter USER ID and Password
3. A separate window will pop-up
   - Disable pop-up blocker on this window
4. Click the Forgot/Change Password to reset your Password
   - Passwords expire after 45 days
   - Password Criteria:
     - 8 characters in length
     - Must contain 3 of the 4 below
       - Uppercase Alpha
       - Lowercase Alpha
       - Numbers
       - Special Characters

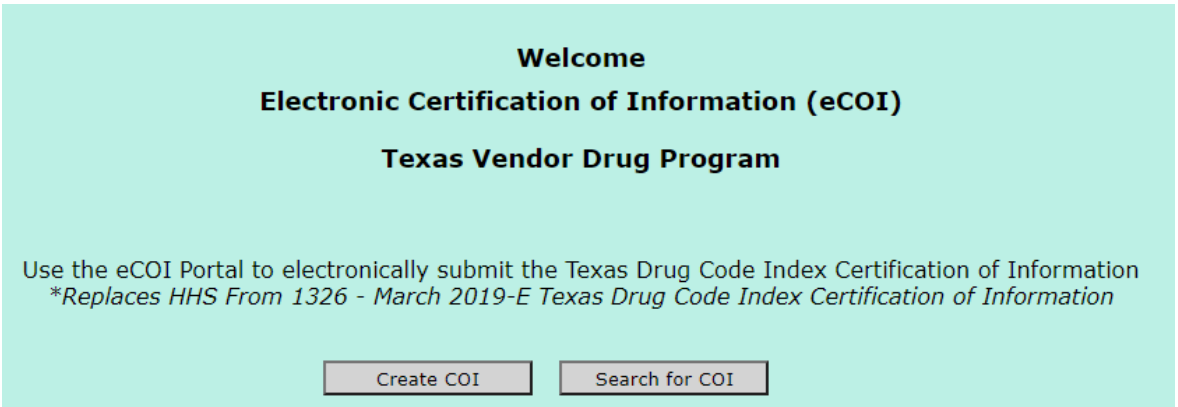
The first time logging in, you will be required to set of security question

8 COI Welcome Screen

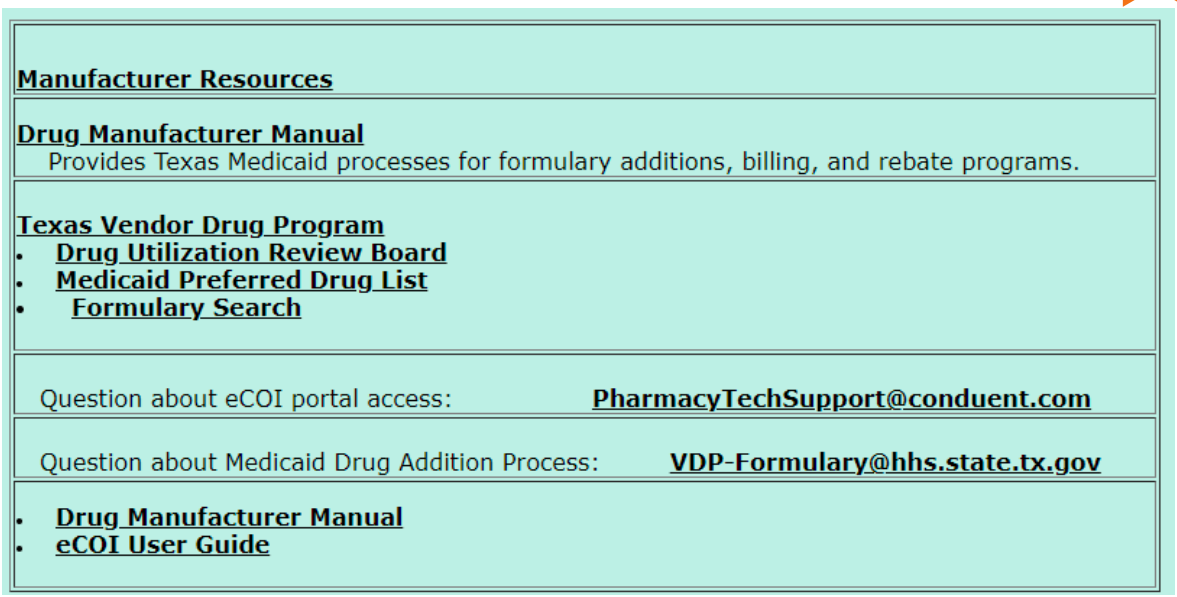


1. User must complete the User Account Details section to continue in the application.
2. Enter the required fields and click SAVE

3. After User Account Details are saved



4. Click Create COI to start a new COI application
5. Click Search for COI if returning to check status of COI or make corrections



6. Use the links to access VDP or other drug related information
7. Use the emails listed for technical support or process questions

9 Creating a new COI application

1. After clicking Create COI, the COI application form will appear
2. Enter the NDC and click FDB button

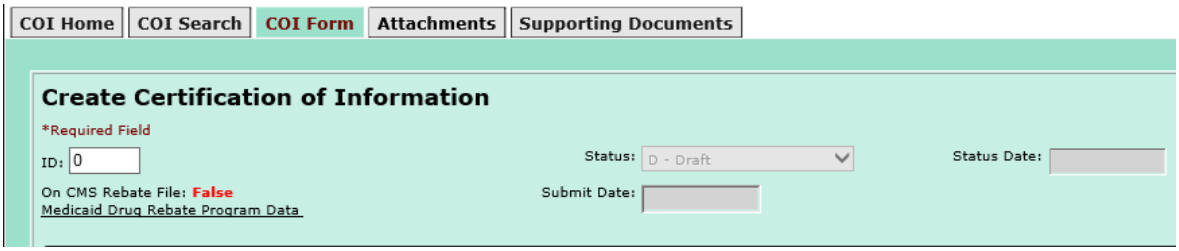
This performs a search to confirm the NDC exists in the HHSC data

2.1. If NDC is not found, this may indicate NDC is not available to HHSC from FDB.

2.2. If NDC is found, the user can manually enter the drug data or copy FDB data by clicking the Copy button

3. Once the user has entered the required drug data, click the CREATE button.

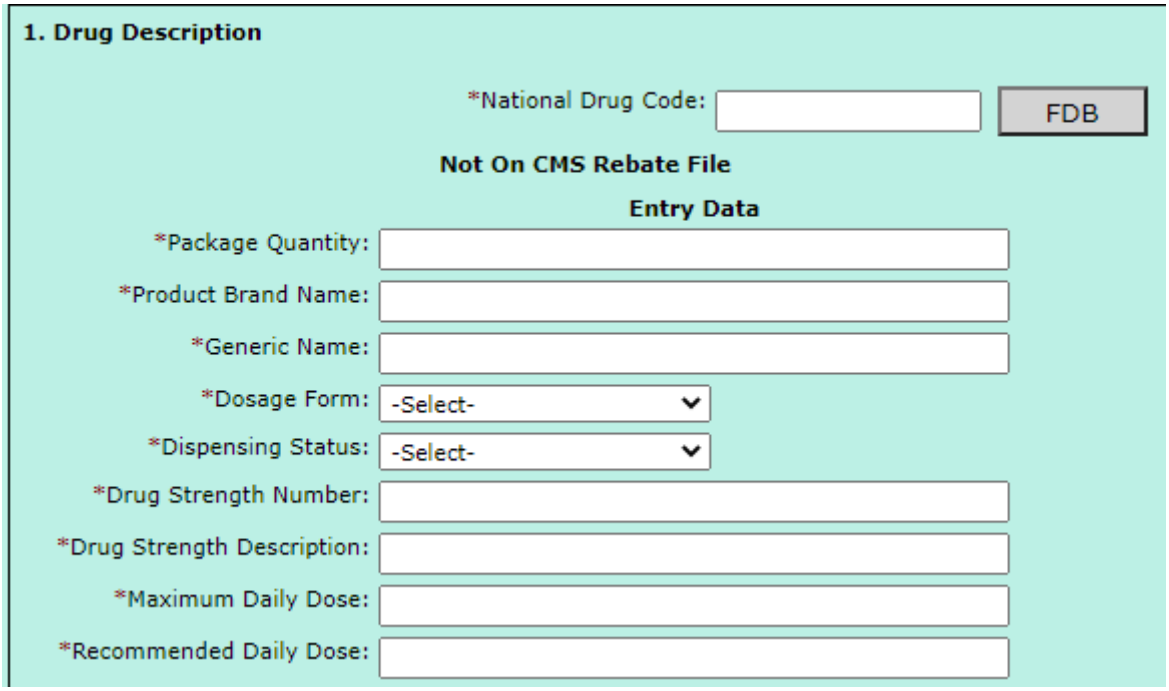
9.1 Header Information explained



Field Name	Values	Descriptions	User Editable
ID	Numeric	Auto-Generated tracking number for each COI created	No

On CMS Rebate File:	True / False	Indicates if NDC entered is present on the previous CMS Rebate File	No
Medicaid Drug Rebate Program Data Link	Link	User can click this link to verify NDC has a drug rebate on the Medicaid.gov website	No
Status	1 – 1st Review 2 - 2nd Review A – Approved C – CMS Pending D – Draft H – Accepted by HHSC I – Initial Status M- Missing Information Hold N – Denied P – Pharmacist Review R – Resubmitted w/o Return T- Texas Formulary U – CMS Updated	**Defined in Section 14**	No
Submit Date	Date	Date the COI was submitted	No
Status Date	Date	Date the status of the COI was updated	No

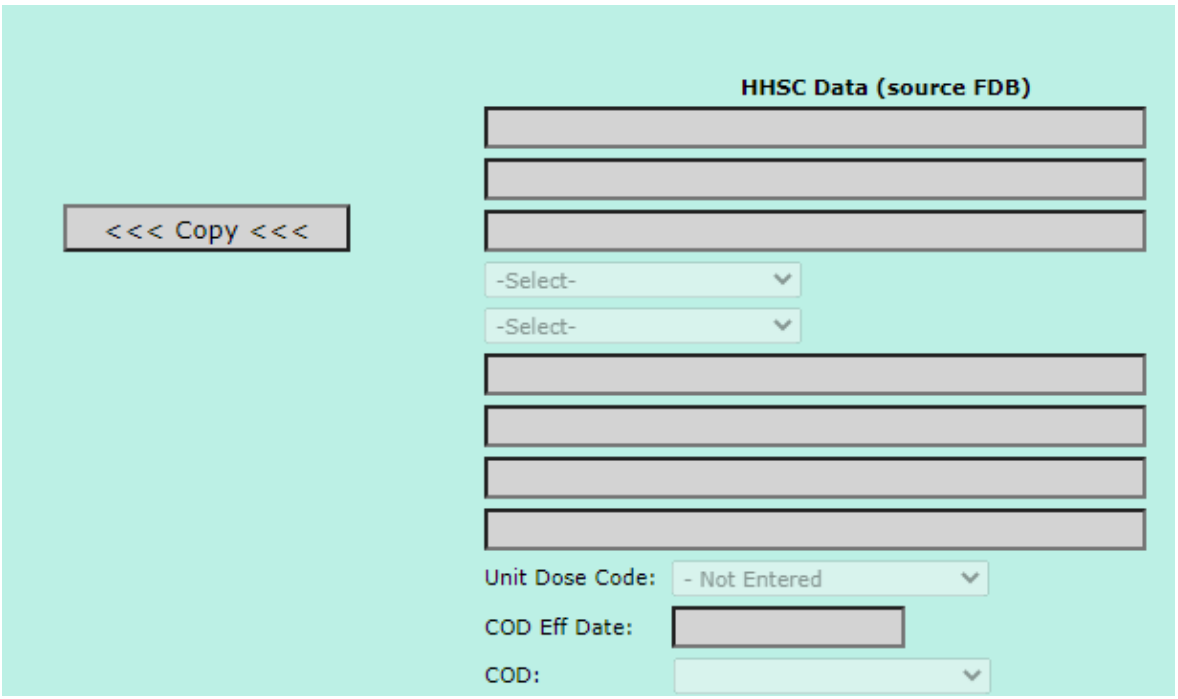
9.2 Left Side Explained



Field Name	Values	Descriptions	Processing Rules	User Editable
National Drug Code	Numeric	NDC of the COI begin created	NDC must exist in FDB NDC cannot be on TX Formulary	Yes
FDB Button		Performs a lookup against OS+ FDB data		No
Package Quantity	User input	Number of units in the NDC packaging (e.g. 300 tablets per bottle)	Required Field	Yes
Product Brand Name	User input	NDC brand name	Required Field	Yes
Generic Name	User input	NDC generic name	Required Field	Yes
Dosage Form	EA, ML, GM	NDC Unit of Measure	Required Field	Yes
Dispensing Status	Legend – (Prescription)	NDC dispensing status	Required Field	Yes

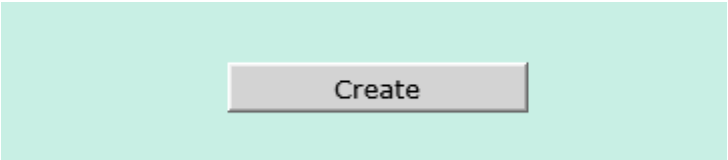
	OTC			
Drug Strength Number	User input	NDC drug strength (e.g. 500) – Only numbers are allowed	Required Field	Yes
Drug Strength Description	User input	NDC drug strength Description (e.g. 500 MG)	Required Field	Yes
Maximum Daily Dose	User input	NDC Max daily dose (e.g. 12 per day)	Required Field	Yes
Recommended Daily Dose	User input	NDC recommended daily dose (e.g. 4 per day)	Required Field	Yes

9.3 Right Side Explained



Field Name	Values	Descriptions	Processing Rules	User Editable
Copy Button		Copies FDB Data to the User editable fields		No
Package Quantity		Number of units in the NDC packaging (e.g. 300 tablets per bottle)	FDB Lookup Data	No

Product Brand Name		NDC brand name	FDB Lookup Data	No
Generic Name		NDC generic name	FDB Lookup Data	No
Dosage Form	EA, ML, GM	NDC Unit of Measure	FDB Lookup Data	No
Dispensing Status	Legend – (Prescription) OTC	NDC dispensing status	FDB Lookup Data	No
Drug Strength Number		NDC drug strength (e.g. 500)	Required Field	Yes
Drug Strength Description		NDC drug strength Description (e.g. 500 MG)	Required Field	Yes
Maximum Daily Dose		NDC Max daily dose (e.g. 12 per day)	FDB Lookup Data	No
Recommended Daily Dose		NDC recommended daily dose (e.g. 4 per day)	FDB Lookup Data	No
Unit Dose Code	0 – All other Prescriptions 1 – Unit Dose	0 – All other Prescriptions 1 – Unit Dose	FDB Lookup Data	No
COD Eff Date	Date	Date COD assigned	FDB Lookup Data	No
COD Code	COD Values	COD Values	FDB Lookup Data	No



Field Name	Values	Descriptions	Processing Rules	User Editable
Create		Creates/Adds the COI to the database to begin process	NDC must be in FDB User must be authorized to	No

		Performs validation steps	create COI for that NDC	

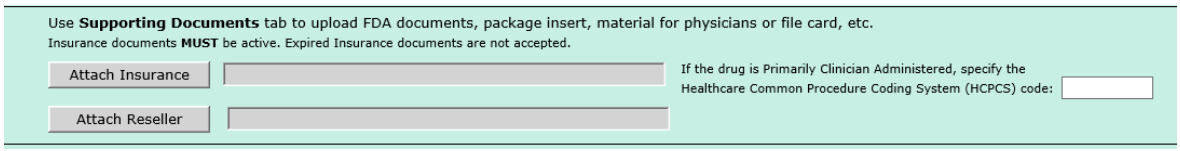
9.4 After clicking Create

After clicking CREATE, the bottom portion of the COI application appears

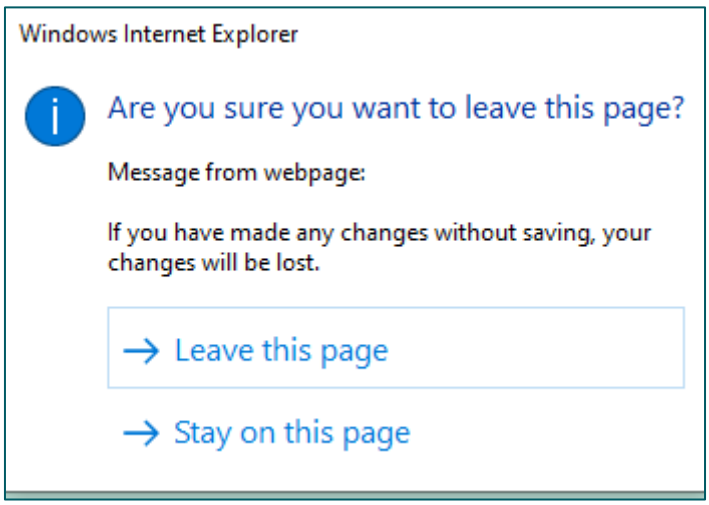
1. Attach a Copy of Certificate of Liability Insurance. Instructions in section 9.4.4
   - **Expired insurance will cause the COI to be returned**
2. Attach Reseller list if the following applies: Instructions in section 9.4.5

▪ Do you sell to distributors, re-packagers or re-labelers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number?

3. If the NDC is a Clinician Administered Drug (CAD), enter the 5-digit Procedure drug associated with the NDC
4. Enter the date the NDC is available on the Market
5. Click Update at bottom of screen

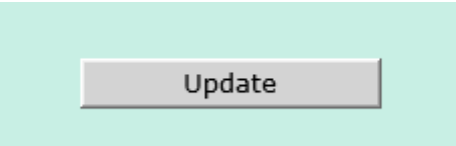


9.5 Pop-Up Leave/Stay Message

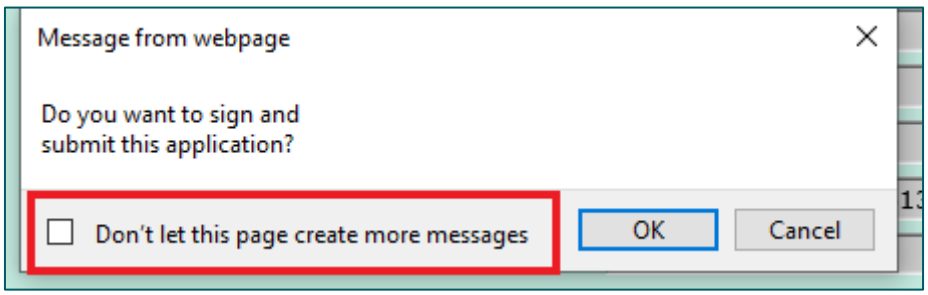


1. If the user encounters the above pop-up message, this indicates there is unsaved data on the COI. If the agent clicks "Leave this Page", the agent will lose any unsaved data.

2. If the user clicks, "Stay on this Page", the user should click UPDATE at the bottom of the page before leaving the form.



9.6 Other Pop-Up Boxes



The agent may encounter other pop-up boxes while using the COI form. These boxes are intended to help mitigate errors by the agent for required fields and signing the application.

IE11 automatically puts a "check box" on the pop-up messages. **DO NOT CHECK** the box. If the box is checked, you may inadvertently disable some of the COI form functions.

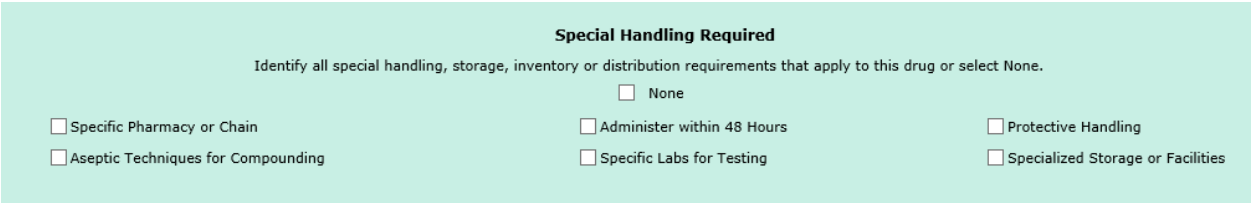
If you do check the box in error, you must restart your browser.

Field Name	Values	Descriptions	Processing Rules	User Editable
Date product available through wholesalers /distributions:	Date	Date NDC is available on the Market		Yes
If the drug is Primarily Clinician Administered, specify the Healthcare Common Procedure Coding System (HCPCS) code:	5-digit HCPCS Code	5-digit HCPCS Code if NDC is an injection		Yes
Attach Insurance Button	User input		Required field	Yes
Attach Reseller Button	User input			Yes

9.7 Special Handling Required

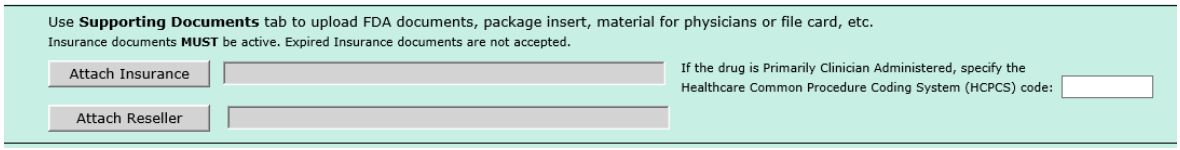
1. The user must identify all special handling, storage, inventory or distribution requirements applicable to this drug by checking one or more applicable boxes.

2. If the NDC does not require special handing, click NONE
   - This section must be completed



Field Name	Values	Descriptions	Processing Rules	User Editable
None	Check	Check if NDC does not require special handling	If checked, no other boxes can be checked	Yes
Specific Pharmacy or Chain	Check	Check if NDC is for a Specific Pharmacy or Chain	Can be checked with other options except none	Yes
Aseptic Techniques for Compounding	Check	Check if NDC requires Aseptic Techniques for Compounding	Can be checked with other options except none	Yes
Administer within 48 Hours	Check	Check if NDC must be Administered within 48 Hours	Can be checked with other options except none	Yes
Specific Labs for Testing	Check	Check if NDC requires Specific Labs for Testing	Can be checked with other options except none	Yes
Protective Handling	Check	Check if NDC requires Protective Handling	Can be checked with other options except none	Yes
Specialized Storage or Facilities	Check	Check if NDC requires Specialized Storage or Facilities	Can be checked with other options except none	Yes

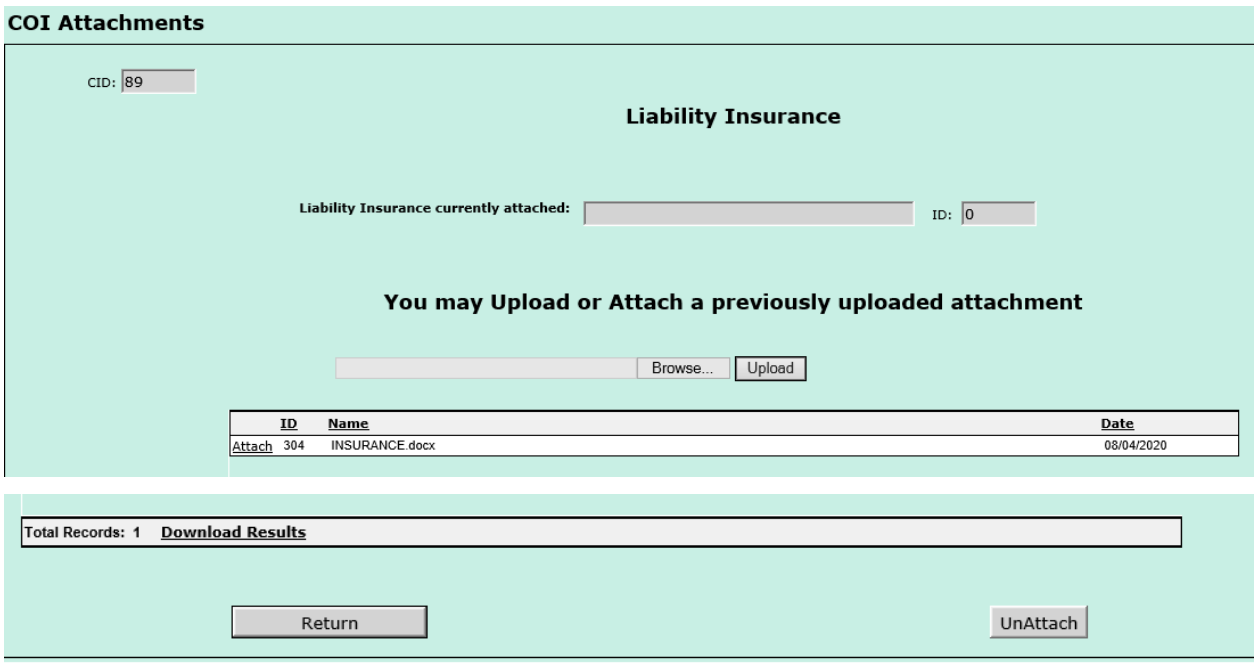
9.8 Attaching Insurance Documents



1. Click "Attach Insurance" button and then "Choose File/Browse" button to search your computer for the Copy of Certificate of Liability Insurance
   - Choose File Button appears in Chrome
   - Browse Button appears in IE
2. Click on the Copy of Certificate of Liability Insurance
   - **Insurance must be active, or COI will be returned**
3. Click Open
4. Click Upload
   - File Name cannot exceed 200 characters
5. Upload Confirmation appears, Click Continue

- If the Copy of Certificate of Liability Insurance has already been uploaded, simply click the "Attach" link to add the Copy of Certificate of Liability Insurance to the current COI application
- If user needs to select a different document, the user can click "UnAttach" and select a new document or upload a new document

6. When upload is complete, select "Return" to return to COI screen



Field Name	Values	Descriptions	Processing Rules	User Editable
CID	Numeric	Auto-Generated tracking number for each document uploaded created		No

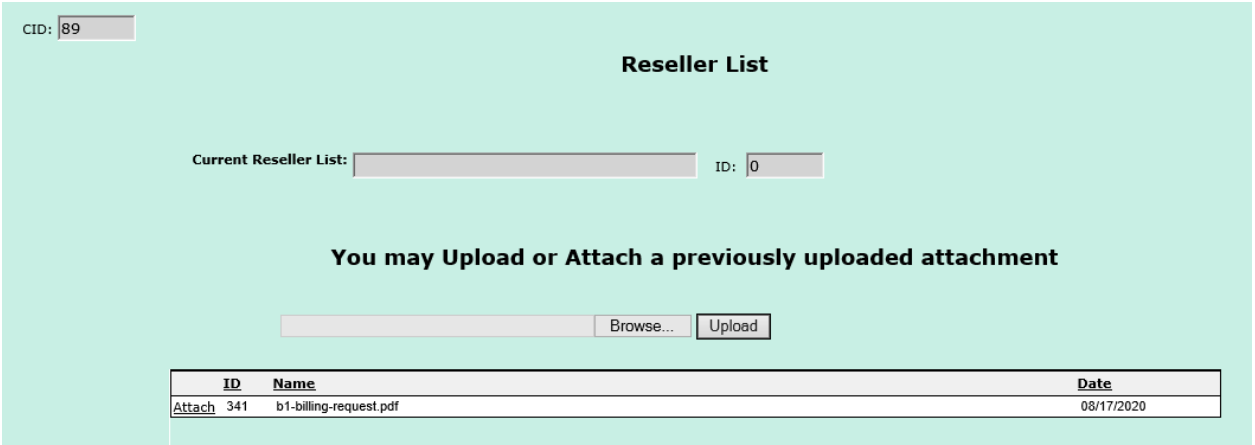
Name	File Name	File name of the document uploaded and attached to the specific COI		No
Choose File/ Browse		Click to locate document to upload		No
Upload		Click to upload selected document		No
Attach		Click to attach a previously uploaded insurance document		No
Return		Returns user back to COI		No
Unattach		Allows user to remove document to allow attaching a different one		No

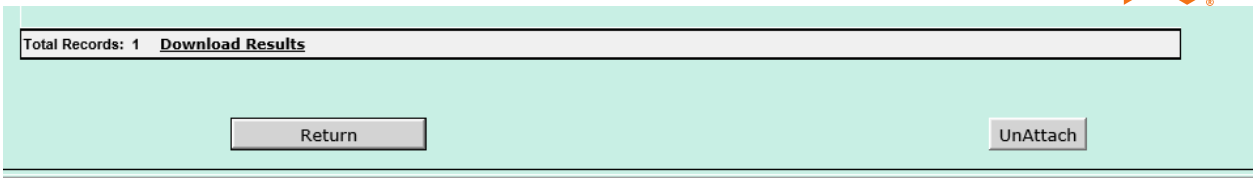
9.9 Attaching Reseller Documents

1. Click Attach Reseller and click the Choose file/Browse button to search your computer for the Reseller List
2. Click on the Reseller List
3. Click Open
4. Click Upload
5. Upload Confirmation appears, Click Continue

- If the Reseller List has already been uploaded, simply click the “Attach” link to add the Reseller List to the current COI application
- If user needs to select a different document, the user can click “UnAttach” and select a new document or upload a new document

6. When upload is complete, select “Return” to return to COI screen



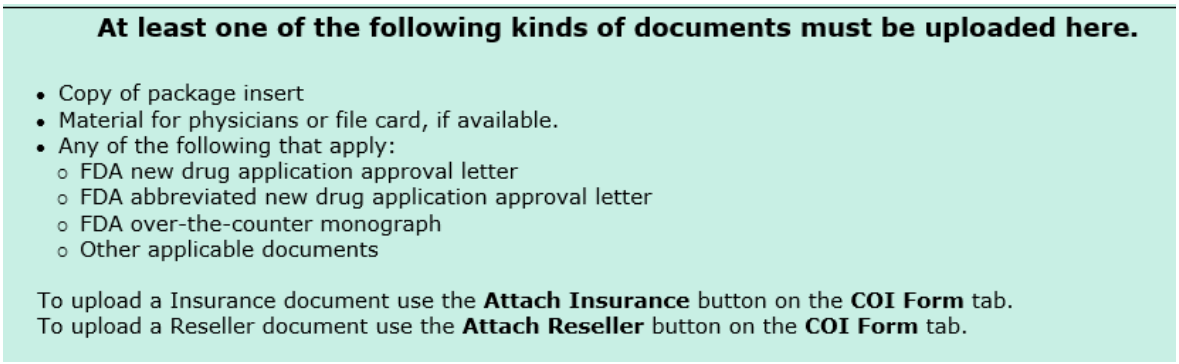


Field Name	Values	Descriptions	Processing Rules	User Editable
CID	Numeric	Auto-Generated tracking number for each document uploaded created		No
Name:	File Name	File name of the document uploaded and attached to the specific COI		No
Choose File/ Browse		Click to locate document to upload		No
Upload		Click to upload selected document		No
Attach		Click to attach a previously uploaded reseller document		No
Return		Returns user back to COI		No
Unattach		Allows user to remove document to allow attaching a different one		No

9.10 Attaching Supporting Documents

At least one document must be uploaded to the Supporting Documents tab

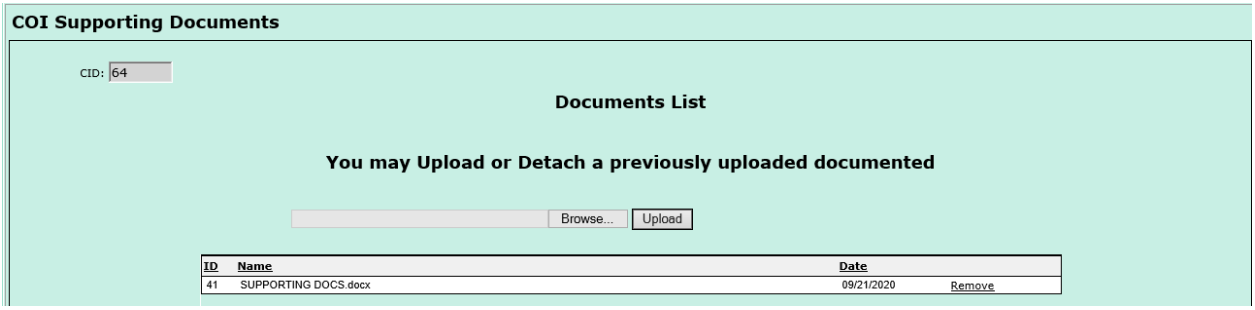
1. Before clicking on Supporting Documents tab, click the **UPDATE** button at the bottom the page
2. Click on the Supporting Documents tab



3. Click the *Browse* button to search your computer for Supporting Documents
4. Click on the Supporting Document to upload

5. Click *Open*
6. Click *Upload*
7. Upload Confirmation appears, Click *Continue*
8. When upload is complete, select "Return" to return to COI screen
9. From COI screen, select "Update" to complete upload

NOTE: If you are ready to submit your application, from COI screen, select ***Submit*** at bottom of page.



Field Name	Values	Descriptions	Processing Rules	User Editable
CID	Numeric	Auto-Generated tracking number for each document uploaded created		No
Name	File Name	File name of the document uploaded and attached to the specific COI		No
Choose File /Browse		Click to locate document to upload		No
Upload		Click to upload selected document		No
Return		Returns user back to COI		No
Remove		Allows user to remove document to allow attaching a different one		No

9.11 Pricing

HHSC uses the National Average Drug Acquisition Cost (NADAC) to calculate pharmacy reimbursement. If NADAC is not available for a product, the reported manufacturer prices are an essential component of HHSC's reimbursement calculation to the pharmacy provider. If a manufacturer leaves a price-point blank within this section, it represents to HHSC the product does not have a price for the price-point. If a manufacturer cannot provide HHSC with a product's average

manufacturer price (AMP) at the initial launch of the product, the manufacturer must provide the AMP to HHSC within 30 days after the close of the calendar quarter for which the AMP is calculated. A manufacturer must provide pricing for any of the prices below within 10 days upon HHSC's request.

1. The user should enter all available pricing for each price point
   - Wholesale/ Distributor pricing is ***REQUIRED***
   - ***Fields must be numeric***
   - Special Characters of "period", "comma", "semi-colon", and "hyphen" are allowed.
   - Spaces and letters are not allowed

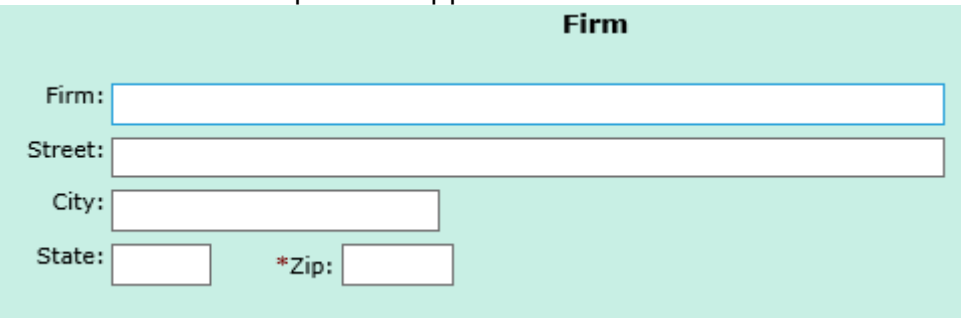
Price terms are defined **in 1 § TAC 354.1921**. Pricing information submitted to HHSC is confidential pursuant to section 354.1921(f). Except for AWP and AMP, "price" means the price net of all price concessions, other than customary prompt pay discounts, for sale of a drug to commercial customers, or for sale of a drug to wholesalers or distributors servicing commercial customers, including chargebacks, rebates or discounts. The manufacturer should report a range of prices if there is no single price for a price point. If the manufacturer reports a price range, it should also include the weighted average of those prices based on unit sales. Include a copy of file card, package insert, and material for physicians. "Pharmacy" means an entity with an approved community pharmacy license or an institutional pharmacy license.

Field Name	Values	Descriptions	Processing Rules	User Editable
Average Wholesale Price (AWP)	User input	Enter the AWP price for the NDC		Yes
AMP	User input	Enter the AWP price for the NDC		Yes
Price to Wholesaler/Distributor	User input	Enter the Wholesaler/Distributor price for the NDC	**Required field**	Yes
Direct Price to Pharmacy	User input	Enter the Direct Price for the NDC		
Weighted Average				

Average Wholesale Price (AWP)	User input	Enter the weighted average AWP price for the NDC		Yes
AMP	User input	Enter the weighted average AWP price for the NDC		Yes
Price to Wholesaler/Distributor	User input	Enter the weighted average Wholesaler/Distributor price for the NDC		Yes
Direct Price to Pharmacy	User input	Enter the weighted average Direct Price for the NDC		Yes

9.12 Firm Contact Information

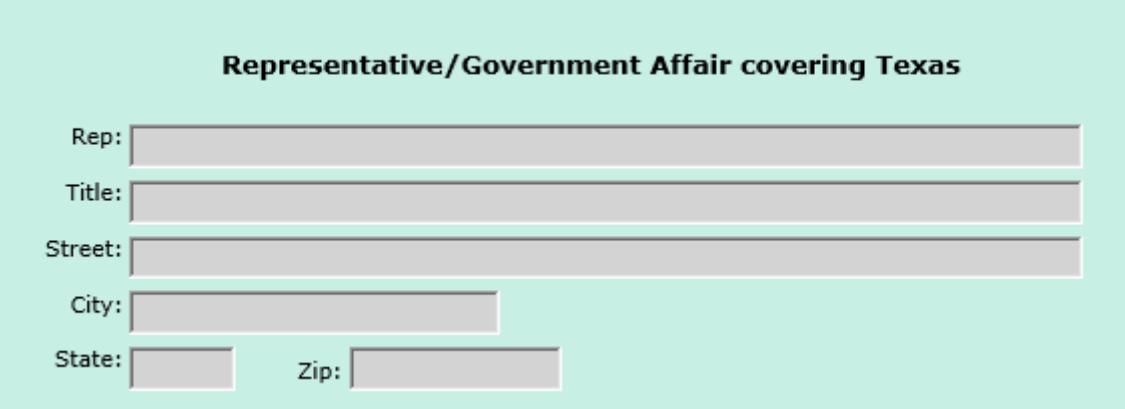
The user should complete all applicable contact information sections.



Field Name	Values	Descriptions	Processing Rules	User Editable
Firm	User input	Enter the name of the Firm the User represents		Yes
Street	User input	Enter the street address		Yes
City	User input	Enter the city		Yes
State	User input	Enter the State Code		Yes
Zip	User input	Enter the 5-digit numeric zip		Yes

9.13 Enter Representative/Government Affair covering Texas

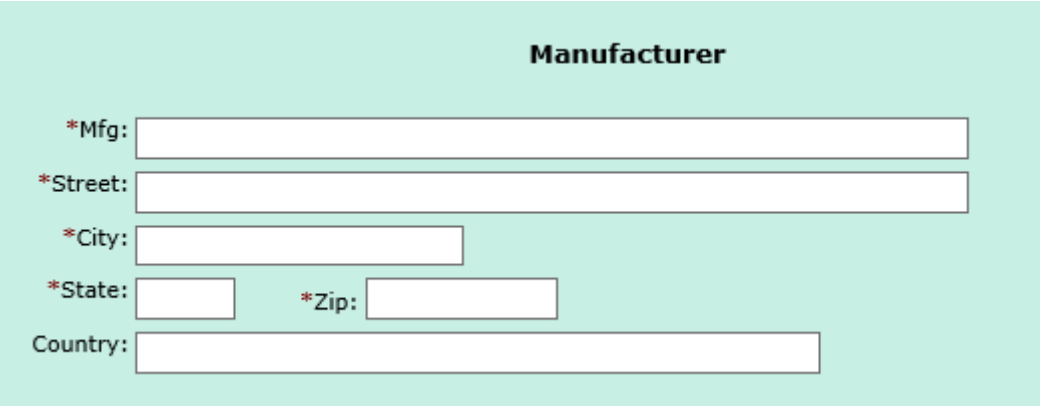
The user should complete all applicable contact information sections



Field Name	Values	Descriptions	Processing Rules	User Editable
Rep	User input	Enter the name of the Representative.	Numbers are not allowed	Yes
Title	User Input	Enter job title of user		Yes
Street	User input	Enter the street address		Yes
City	User input	Enter the city		Yes
State	User input	Enter the State Code		Yes
Zip	User input	Enter the 5-digit numeric zip		Yes

9.14 Enter Manufacturer Information

1. The user **MUST** complete the Manufacturer contact section



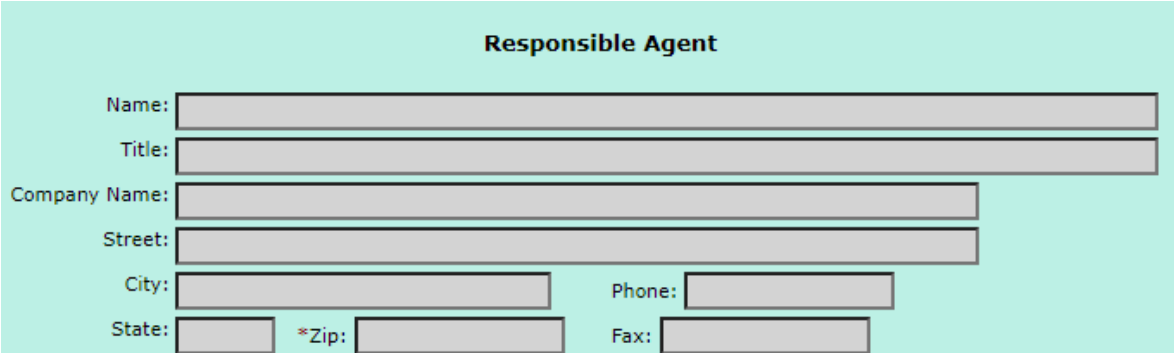
Field Name	Values	Descriptions	Processing Rules	User Editable
Mfg	User input	Enter the name of the Manufacture	Required	Yes
Street	User input	Enter the street address	Required	Yes
City	User input	Enter the city	Required	Yes

State	User input	Enter the State Code	Required	Yes
Zip	User input	Enter the 5-digit numeric zip	Required	Yes
Country	User input	Enter country	Not required	Yes

9.15 Responsible Agent Information

Responsible Agent is defined as a person with legal authority to make the statement on behalf of and with the authority to legally bind the manufacturer listed under; Section 3. Contacts; to the statement listed under; Section 4.Certification

1. The user logged into the COI application will be the Responsible Agent for the COI. This information is populated based on the information entered when first opening the COI application. When the **UPDATE** button is clicked, this section is populated.
    - Note: If another users information has already been populated, the current user will **REPLACE** the previous users information. The current user will become the **NEW** Responsible Agent.



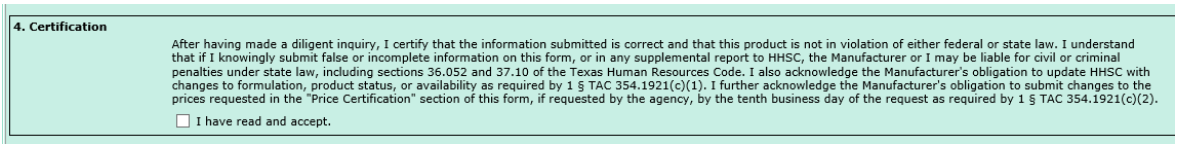
Field Name	Values	Descriptions	Processing Rules	User Editable
Name	User input	Enter the name of the User completing the COI	Required – Numbers are not allowed	Yes
Title	User input	Enter job title	Required	Yes
Company Name	User input	Enter company name	Required	Yes
Street	User input	Enter the street address	Required	Yes
City	User input	Enter the city	Required	Yes
State	User input	Enter the State Code	Required	Yes

Zip	User input	Enter the 5-digit numeric zip	Required	Yes
Phone	User input	Enter 10-digit phone number	Required	Yes

9.16 Certifying the COI

After having made a diligent inquiry, I certify the information submitted is correct and this product is not in violation of either federal or state law. I understand if I knowingly submit false or incomplete information on this form, or in any supplemental report to HHSC, the Manufacturer or I may be liable for civil or criminal penalties under state law, including sections 36.052 and 37.10 of the Texas Human Resources Code. I also acknowledge the Manufacturer's obligation to update HHSC with changes to formulation, product status, or availability as required by 1 § TAC 354.1921(c)(1). I further acknowledge the Manufacturer's obligation to submit changes to the prices requested in the "Price Certification" section of this form, if requested by the agency, by the tenth business day of the request as required by 1 § TAC 354.1921(c)(2).

1. The user should read and check the “I have read and accept” box

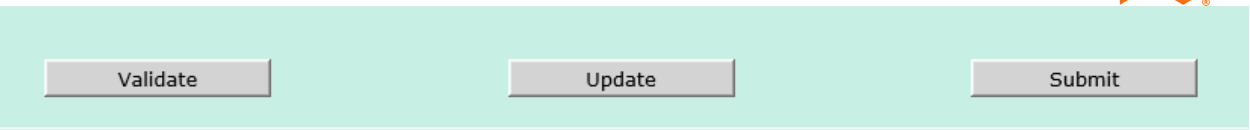


Field Name	Values	Descriptions	Processing Rules	User Editable
I have read and accept	User input	Check the box to certify the COI	Required	Yes

9.17 COI Form Buttons

The user can Validate the COI, Update the COI or Submit the COI

- Validating the COI performs a check for missing information only, and not the actual data itself. Recommend validating prior to each update and /or submittal
- Updating the COI allows the user to save their work or perform updates to the information in the COI after it has been submitted. Pricing updates are only allowed. No other COI fields can be changed.
- Submit allows the user the send the COI application to HHSC for review

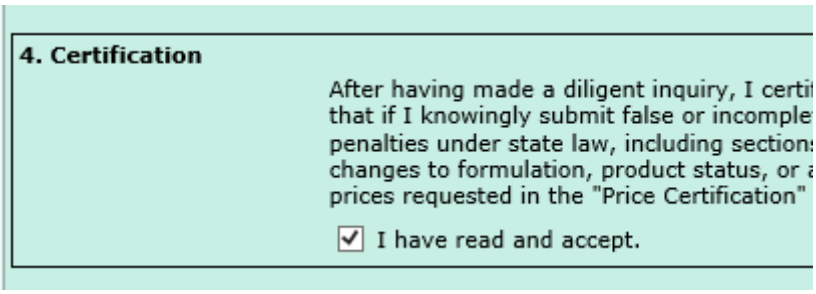


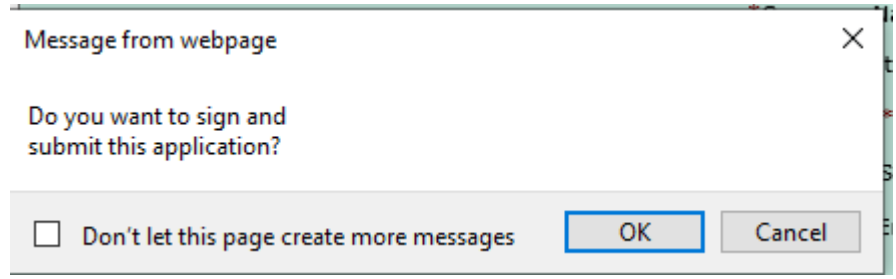
Field Name	Values	Descriptions	Processing Rules	User Editable
Validate	User input	Clicking validate checks the form for any missing required fields. Prompts user to the missing fields for input		
Update	User input	Clicking Update saves the form		
Submit	User input	Clicking Submit will prompt the user to sign the COI form with an email address		

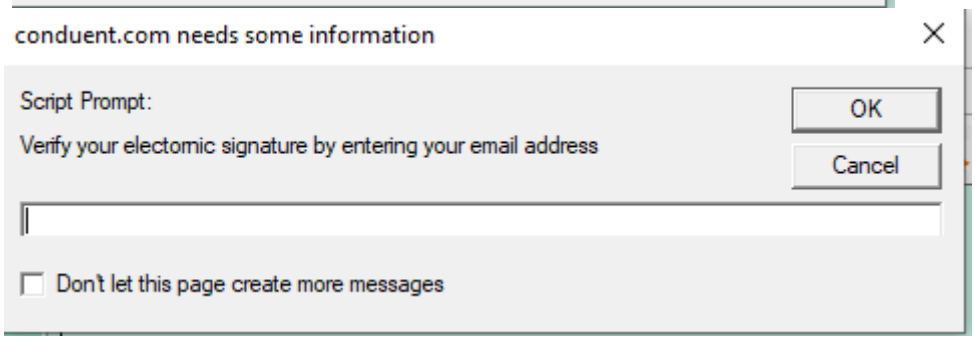
9.18 Submitting the COI Application

After the user has verified everything is complete and accurate and has checked the "I have read and accept box"

1. Click Submit
2. Confirm submitting the application
3. Click OK
4. Enter the users email address exactly as provided during the registration process
    - If the email does not match the registration email, the COI application cannot be submitted





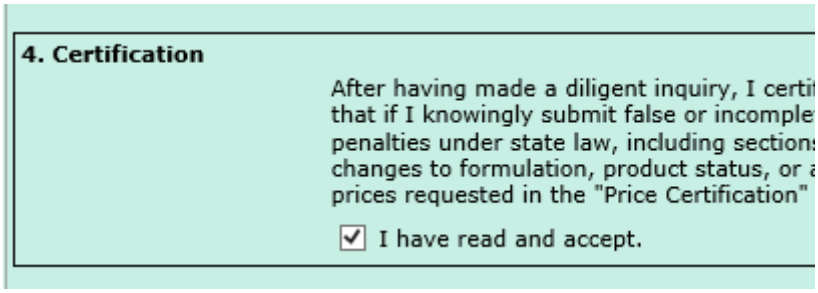


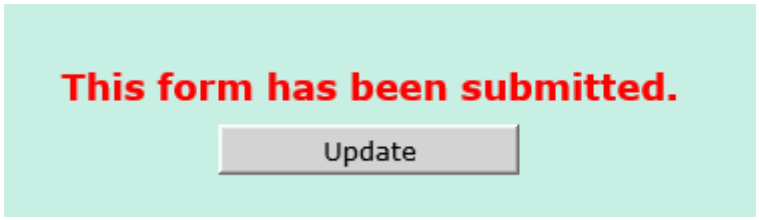
Field Name	Values	Descriptions	Processing Rules	User Editable
Prompt	Ok / Cancel	User clicks OK to proceed to sign COI	Must click OK to proceed	No
Enter Email	Email	Email entered must match the email address the user signed in to submit the COI. Email may not be the creator	Email must match	No

10 Updating the COI after Submission

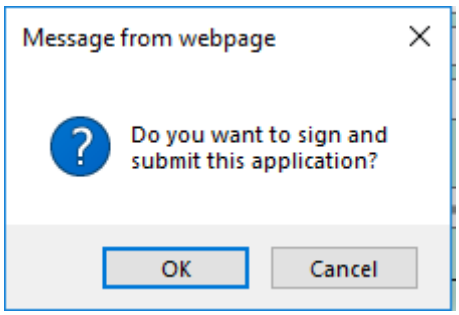
The user can only update pricing and supporting documents

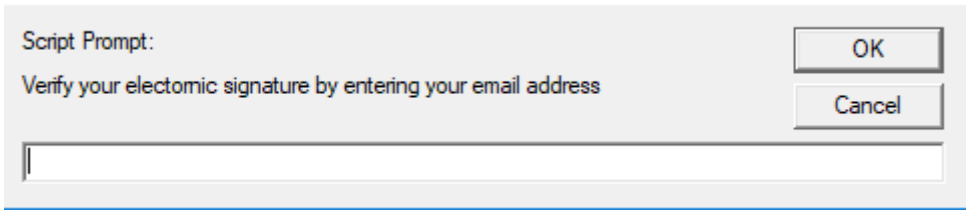
1. Make all necessary changes
2. Check the "I have read and accept box"
3. Click Update
4. Enter the users email address exactly as provided during the registration process
    - If the email does not match the registration email, the COI application cannot be submitted





Field Name	Values	Descriptions	Processing Rules	User Editable
Update		Allows user to update COI data after submitting COI. User must check *I have read and accept* and resign the COI		No

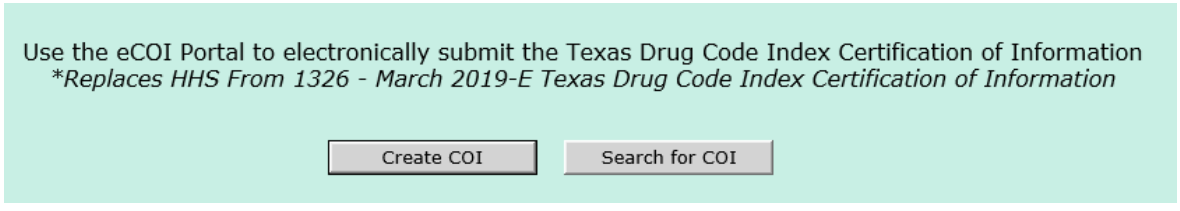




11 Search for Existing COI

The user can search for an existing COI application to make updates, review status, or to clone an existing COI application

1. Click Search for COI



Button Name	Function
Create COI	Opens screen for User to create a new COI

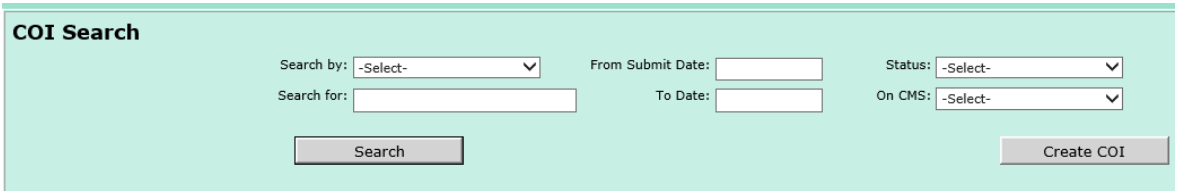
Search for COI	Allows User to search for an existing COI

11.1 Search for COI Criteria

The user has many ways to search for an existing COI application

- NDC
- Label Code
- COI Number
- Brand Name
- On CMS

1. Select and enter the search criteria and click the search button



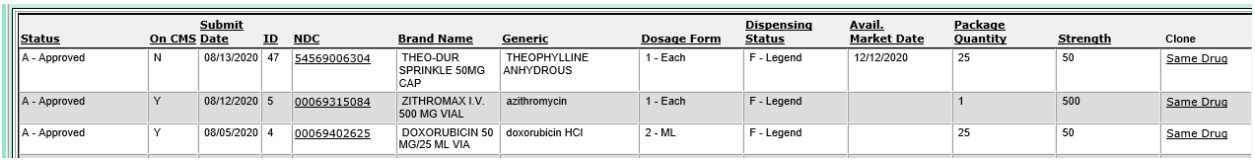
Field Name	Values	Descriptions
Search By	NDC Label Code COI Number Brand Name	User can search for a COI by selecting one of the Search By criteria
Search For	User Input	User enters criteria to search for COI
From Submit Date	User Input	User enters a begin date range to search for COI
From Submit To Date	User Input	User enters an end date range to search for COI
Status	User Input	User selects a status of the COI to search for 1 – 1st Review 2 - 2nd Review A – Approved C – CMS Pending D – Draft F – FDB Pending H – Accepted by HHSC

		I – Initial Status M- Missing Information Hold N – Denied P – Pharmacist Review R – Resubmitted w/o Return T- Texas Formulary U – CMS Updated
On CMS	Yes/No	Shows NDCs by CMS status based on latest CMS rebate file

11.2 Search Results

Based on the search criteria entered, the system will display the COIs meeting the users criteria

1. Sort the columns by clicking on the column headers
2. Click on the NDC to open the COI application



Status	On CMS	Submit Date	ID	NDC	Brand Name	Generic	Dosage Form	Dispensing Status	Avail. Market Date	Package Quantity	Strength	Clone
A - Approved	N	08/13/2020	47	54569006304	THEO-DUR SPRINKLE 50MG CAP	THEOPHYLLINE ANHYDROUS	1 - Each	F - Legend	12/12/2020	25	50	Same Drug
A - Approved	Y	08/12/2020	5	00069315084	ZITHROMAX I.V. 500 MG VIAL	azithromycin	1 - Each	F - Legend		1	500	Same Drug
A - Approved	Y	08/05/2020	4	00069402625	DOXORUBICIN 50 MG/25 ML VIA	doxorubicin HCl	2 - ML	F - Legend		25	50	Same Drug

Field Name	Values	Descriptions
Status	1 – 1st Review 2 - 2nd Review A – Approved C – CMS Pending D – Draft H – Accepted by HHSC I – Initial Status M- Missing Information Hold N – Denied P – Pharmacist Review R – Resubmitted w/o Return T- Texas Formulary	Current Status of the COI

	U – CMS Updated	
On CMS	Y / N	Indicates if NDC is on latest CMS rebate file
Submit Date	Date	Date COI was last submitted
ID	COI Number	COI Number
NDC	NDC entered on COI	NDC of the COI
Brand Name	Brand Name entered on COI	NDC Brand Name
Generic Name	Generic Name entered on COI	NDC Generic Name
Dosage Form	EA, ML, GM	NDC Unit of Measure
Dispensing Status	Legend – (Prescription) OTC	NDC dispensing status
Avail Market Date	Date entered on COI	Date NDC is available on the Market
Package Quantity	Package Quantity entered on COI	Number of units in the NDC packaging (e.g. 300 tablets per bottle)
Strength	Strength entered on COI	NDC drug strength (e.g. 500mg)
Clone	Link	Allows user to create a new COI using data from current COI

11.3 Cloning COI

The user can clone an existing COI application when the information on an existing COI application is identical to the information on a new COI application, except the NDC.

1. Click on the "Same Drug" link
2. Change the NDC to a new value
3. Click FBD button
4. Click "Copy" to transfer FDB data to the NDC details
5. Click CREATE

Cloning copies the following fields into a new COI. All other required fields will need to be entered by User

- Insurance Attachment
- Reseller Attachment
- Firm Contact
- Representative/Government Affairs Contact

- Manufacturer Contact
- Responsible User Contact

Field Name	Descriptions
NDC	User will change NDC for new COI
Insurance Attachment	User can review or replace attachment
Reseller Attachment	User can review or replace attachment
Firm Contact	User can modify contact information
Representative/Government Affairs Contact	User can modify contact information
Manufacturer Contact	User can modify contact information
Responsible User Contact	User can modify contact information

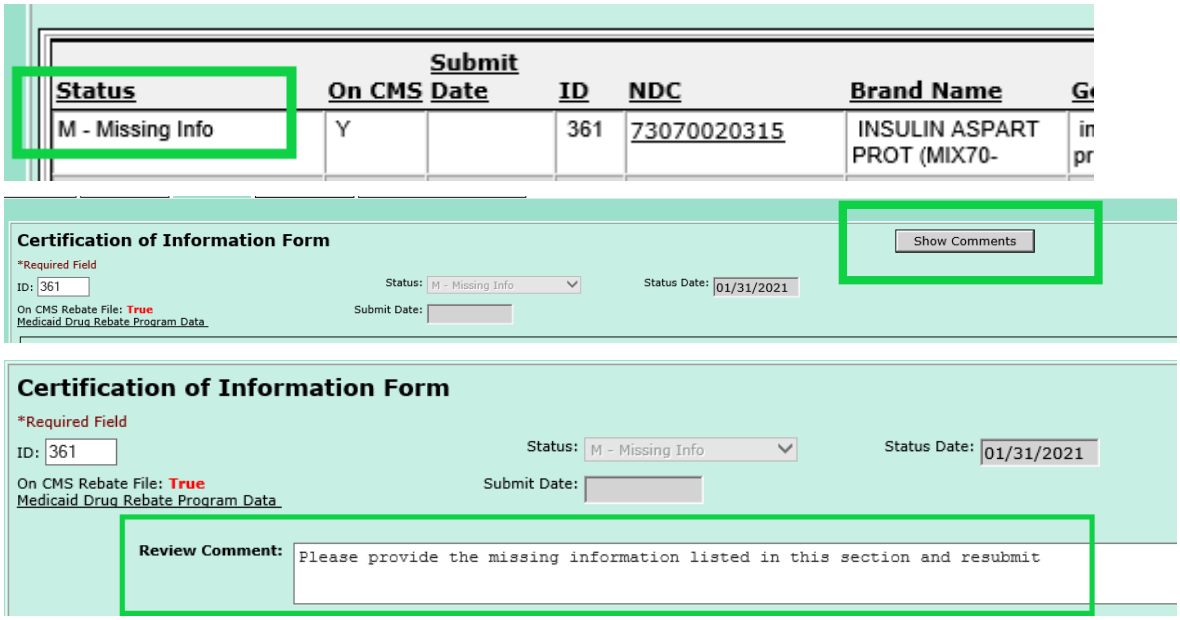
12 Correcting a Returned COI Application

HHSC will review each COI application for compliance. In the event HHSC discovers missing or incorrect information related to the submitted COI application, HHSC will return the COI to the user.

The status of a returned COI application is "**Missing Information Hold**"

The user should check the status of their COI applications for any returned COIs in this status. The user has **10-business days** to correct and resubmit the COI application, or the COI will be denied, and a new COI application is required.

The agent will receive an email indicating more information is needed. The agent should click "Show Comments" and read the "Reviewers Comments" within the specific COI to determine what information is needed



Example Email

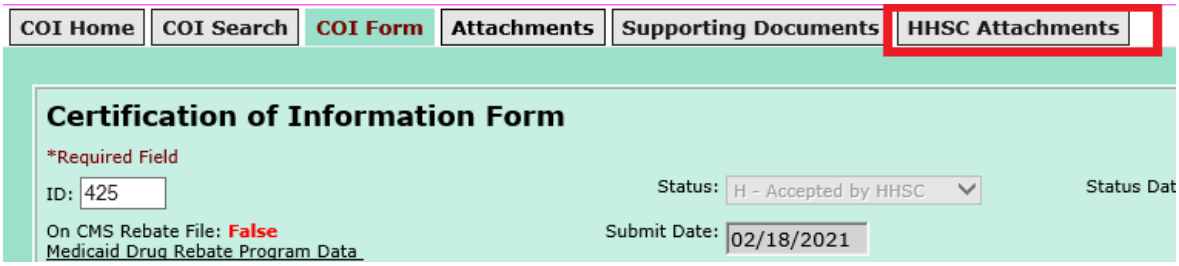
Thank you for your application to add drugs to the Texas Formulary. This letter is to inform you that your eCOI has been returned and requires additional information. Please refer to the Review Comment to identify what information is needed.

URGENT: You must provide the information within 10 days or your eCOI will be automatically denied.

COI#	NDC Number	Product Name	Information Missing Date
361	73070020315	INSULIN ASPART PROT (MIX70-	01/31/2021

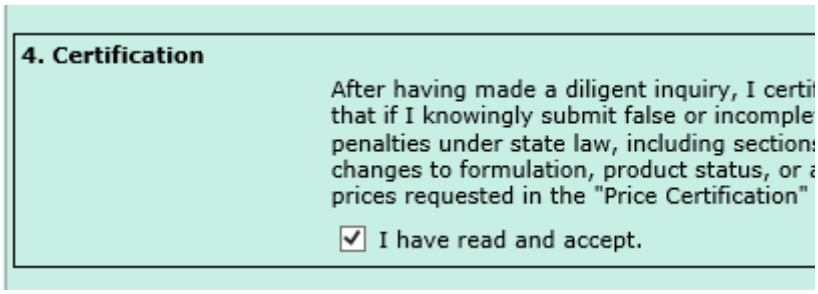
12.1 HHSC documentation to review

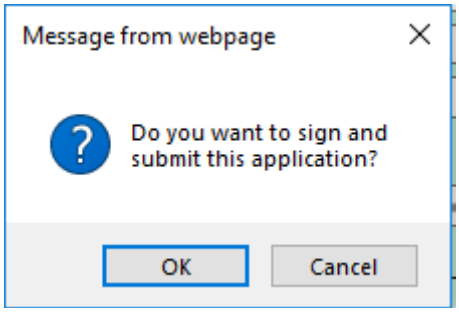
HHSC can attach documents to the HHSC Attachments tab for your review. When reviewing a missing information COI, please check this tab for additional information.

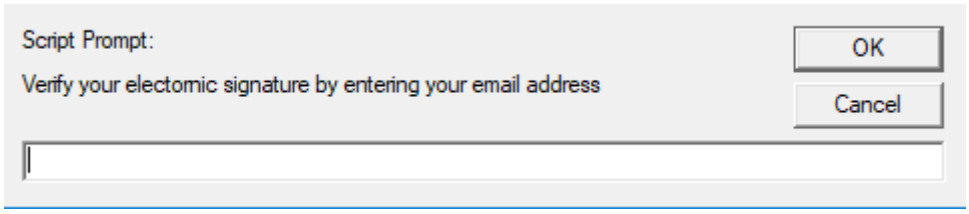


12.2 Correction Steps

1. Make all necessary changes
2. Check HHSC Attachments for possible additional information
3. Click Verify
4. Check the "I have read and accept box"
5. Click Submit
6. Enter the users email address exactly as provided during the registration process
    - If the email does not match the registration email, the COI application cannot be submitted







13 COI Status Definitions

Status	Definition
D- Draft	Status of the COI before saving by the User
I – Initial Status	Status of the COI after saving by the User, but before the COI has been submitted to HHSC
H – Accepted by HHSC	COI has been submitted to HHSC and is awaiting review
1 – 1st Review	HHSC has performed the initial review of the COI
2 – 2nd Review	HHSC has performed the 2nd review of the COI
P – Pharmacist Review	HHSC has performed the 3rd review of the COI and is awaiting a pharmacist to give final approval
C – CMS Pending	HHSC has received the COI and the NDC is not on the last CMS rebate file.
U – CMS Updated	The NDC was not originally on the latest CMS rebate file and has since appeared on the file in a subsequent quarter
M- Missing Information Hold	HHSC has reviewed the COI and has determined additional information is needed from the User to complete the review. Notes will provide User with the required information. User must resubmit the COI.
A – Approved	HHSC has approved the COI
T- Texas Formulary	HHSC has added the NDC to the Texas Formulary for program coverage
N – Denied	HHSC has denied the COI and provided notes to the User as to why. HHSC denial can also be due to CMS Pending or Missing Information

R – Resubmitted w/o Return	User has updated the COI without HHSC asking for an update. This could be to update pricing or contact information

14 Approved COIs

When a COI is approved and added to the TX Formulary for benefit coverage. The agent will receive an email confirming benefit coverage and the coverage start date.

Example Email

Dear TX ,

Thank you for your application to add drugs to the Texas Formulary. This letter is to inform you that the drug NDC listed below has been approved for inclusion in the Texas Formulary. Claims submitted for clients for dates of service on or after the effective date listed below will be reimbursable through the Texas Vendor Drug Program.

COI#	NDC Number	Product Name	Date Added to Formulary
43	60687024940	LEVETIRACETAM 500 MG/5 ML S	12/31/2020

15 Denied COIs

In the event the COI is denied, the user will receive an email indicating the reason for the denial. To view the denial reason in the application, the Agent must open the denied COI, and scroll to the bottom of the screen. The denial reason(s) will be listed.

Example Email

This will advise you that your application for INSULIN ASPART PROT (MIX70- for inclusion on the Texas Vendor Drug Program has been denied.

Denied Reason(s)
1. This product has been determined to be a Clinician Administered Drug. If you need further information on the process of adding your product to our CAD formulary or for CAD benefits please contact VDP-CAD@hhsc.state.tx.us. Per TAC RULE §354.1923 (c)(17)
2. This product is indicated for weight control, Per TAC RULE §354.1923 (c)(1)
3. This product is listed as COD: 12- Unapproved Drug, Per 1927(k)(2)(A)(ii) of the Social Security Act
4. Drugs included in the irrigating set class, Per TAC RULE §354.1923 (c)(12)

COI#	NDC Number	Product Name	Denied Date
321	73070020310	INSULIN ASPART PROT (MIX70-	01/26/2021

Denial Reasons

Reason	Description
Irrigating Set Class	Drugs included in the irrigating set class, Per TAC RULE §354.1923 (c)(12)
COD12	This product is listed as COD: 12- Unapproved Drug, Per 1927(k)(2)(A)(ii) of the Social Security Act
Weight Control	This product is indicated for weight control, Per TAC RULE §354.1923 (c)(1)
CAD Drug	This product has been determined to be a Clinician Administered Drug. If you need further information on the process of adding your product to our CAD formulary or for CAD benefits please contact VDP-CAD@hhsc.state.tx.us. Per TAC RULE §354.1923 (c)(17)

If the COI is denied, the agent can resubmit a new COI for the same NDC if original information submitted was incorrect or wanting HHSC reconsideration.

15.1 Denied Reasons

Current list of possible denial reasons

1. This product is available in unit-dose packaging Per TAC RULE §354.1923 (c)(23)

2. This product is determined to be a clinician-administered drug. If you need further information on the process of adding your product to our CAD formulary or for CAD benefits please contact VDP-CAD@hhsc.state.tx.us. Per TAC RULE §354.1923 (c)(17)
3. This product is indicated for weight control, Per TAC RULE §354.1923 (c)(1)
4. This product listed as COD: 9-OTC Monograph Tentative with CMS
5. This product is listed as COD: 12- Unapproved Drug, Per 1927(k)(2)(A)(ii) of the Social Security Act
6. Drugs included in the irrigating set class, Per TAC RULE §354.1923 (c)(12)
7. Drugs indicated for Erectile Dysfunction are not approved for inclusion to our Texas drug formulary as stated in Section 1927 (d)(2)(k) of the Social Security Act
8. Agent failed to respond within 10-days for missing information
9. NDC does not have an active CMS rebate agreement
10. Any other reason(s) as defined by HHSC

15.2 HHSC documentation to review

HHSC can attach documents to the HHSC Attachments tab for your review. When reviewing a denied COI, please check this tab for additional information.