HEALTH PLAN MANAGEMENT SYSTEM

FORMULARY SUBMISSION MODULE & REPORTS TECHNICAL MANUAL (PLAN VERSION)

MARCH 27, 2009

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INTRODUCTION

Since the implementation of the Medicare Part D benefit, the Health Plan Management System (HPMS) has provided various utilities to support the submission, review, and approval of the Bid and Formulary Submission for organizations offering the Medicare Part D benefit. The Formulary Submission Module in HPMS enables plans to submit one or more formulary files for a contract that contains all or a subset of drugs from the CMS provided Formulary Reference File.

The purpose of this Formulary Submission Module & Reports Technical Manual is to provide step-by-step instructions on how to submit, delete or revise plan formularies. It also provides instructions on how to submit supplemental files associated with a formulary (such as the Gap Coverage or Excluded Drugs files) and to generate reports to monitor the status of formulary submissions.

This Manual will help you step through the Formulary Submission module to provide information to help you to:

- Associate Contract Numbers to a Formulary.
- Enter your Formulary Information, e.g. Formulary, Tier Information, etc.
- Monitor your Formulary Status using Formulary Reports.

The HPMS Formulary Submission Module is made available to organizations in March. CY 2010 Formulary Submissions are due April 20, 2009. It is highly recommended that organizations submit their formulary file(s) as early as possible during the upload timeframe. Uploading earlier in this time frame will provide organizations with adequate time to address potential upload problems and submit corrected formulary file(s). An organization may resubmit its formulary as many times as necessary during the initial upload period, however, only the final successful submission will be processed for CMS review. Organizations implementing a formulary must provide a formulary file, along with the applicable supporting documentation (e.g. prior authorization attachment and/or step therapy attachment).

On June 8, 2009, the Formulary Supplemental Submissions and Reports functionality will be released to support the submission of gap coverage, free first fill, home infusion, over-the-counter, and excluded drug supplemental files. Organizations must submit this supplemental information for each plan offering this coverage. The supplemental files cannot be loaded until the organization has successfully submitted their related bid(s). The supplemental files will be due 5 – 10 days after the bid submission window ends. Details on the required file format are available in Appendix B.

If you have any questions about accessing the HPMS Formulary Submission Module, contact the HPMS Help Desk at 1-800-220-2028.

I. GETTING STARTED

ACCESSING THE HPMS

The HPMS Formulary Submission module is hosted on a secure extranet site that you can access via the Internet using a Secure Sockets Layer (SSL) Virtual Private Network (VPN). You can also access HPMS by dial-up or T1/leased line via the Medicare Data Communications Network (MDCN).

CMS USER IDS

You must have a CMS-issued User ID and password approved for HPMS access in order to log into the system. You must also request that your contract numbers be associated with your user ID in order to submit your data.

> To obtain a new CMS User ID you must fill out a CMS User ID request form. You can download and print the form from the following URL: http://www.cms.hhs.gov/AccesstoDataApplication/Downloads/Access.pdf.

If you are an existing HPMS plan user and need to associate a contract number to your current CMS User ID, please include the following information in an email to hpms_access@cms.hhs.gov:

- User Name,
- CMS User ID,
- Current Contract Number(s), and
- Contract Number(s) to be added.

All questions related to HPMS user access should be directed to hpms_access@cms.hhs.gov.

HOW TO ACCESS THE HPMS HOME PAGE USING THE INTERNET

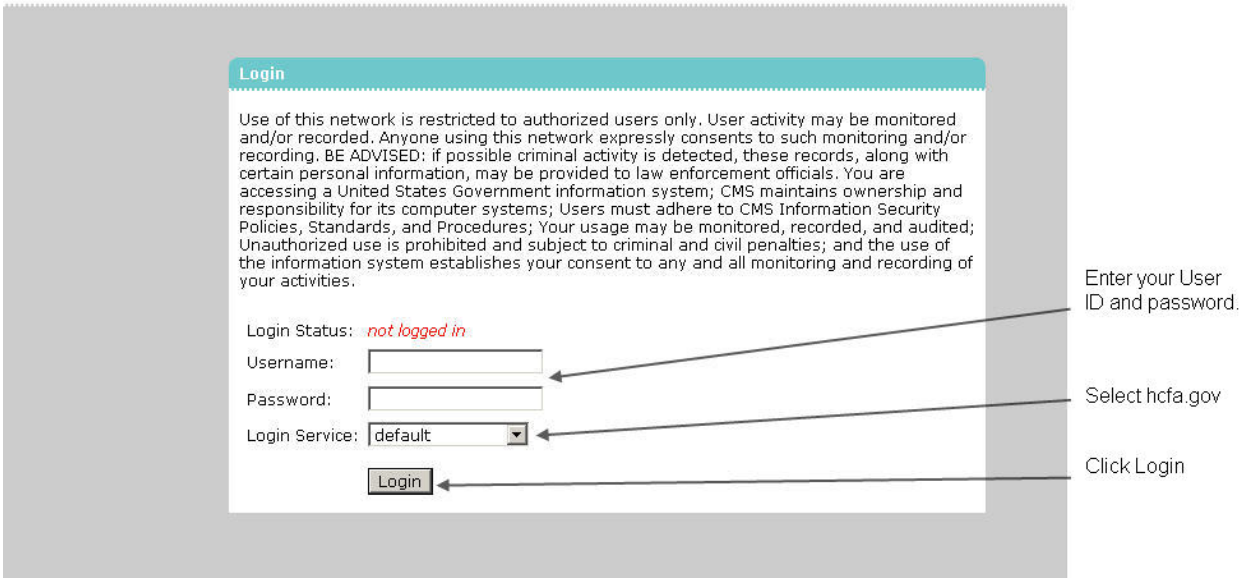
STEP 1

Open your web browser (e.g., Internet Explorer) and enter the CMS SSL VPN gateway address https://gateway.cms.hhs.gov in the Address bar.

STEP 2

Enter your CMS User ID and password and select "hcfa.gov" as the login service. Click on the **Login** button (see Table I-1).

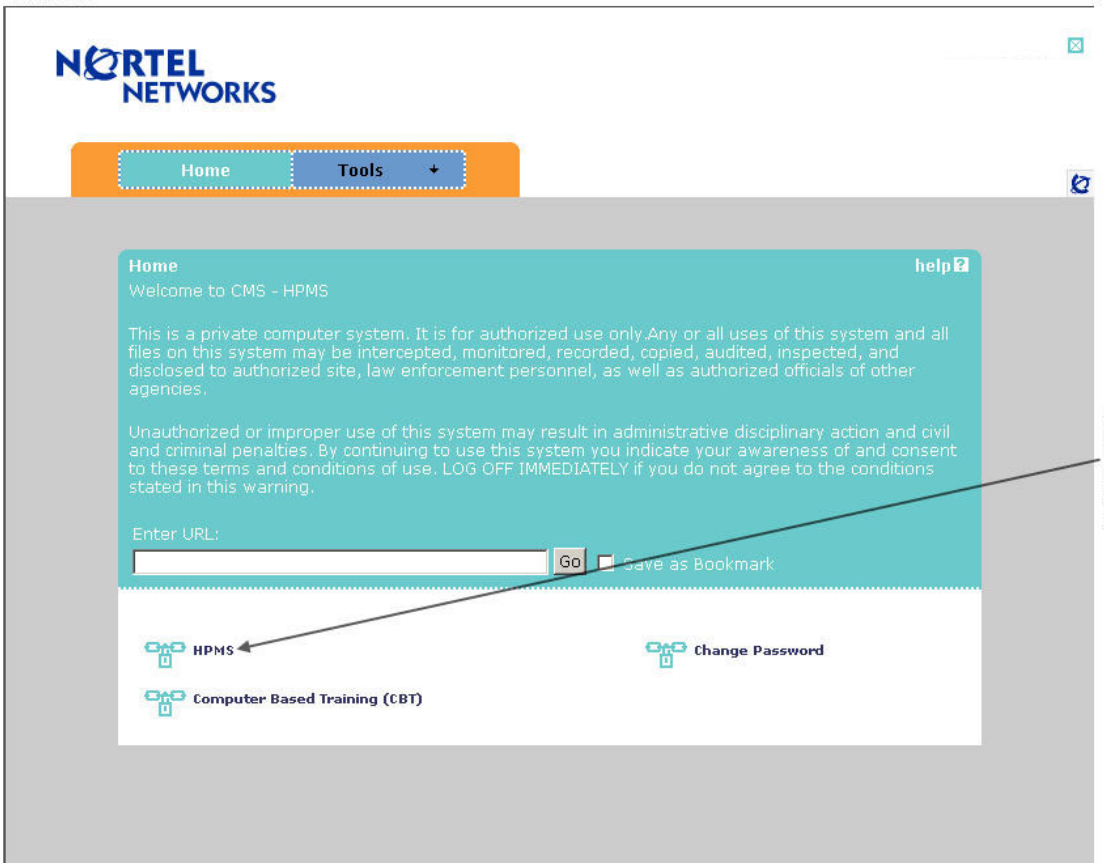
Table I-1



STEP 3

Select the **HPMS** link from the SSL VPN portal page to access the **HPMS Home Page** (see Table I-2).

Table I-2



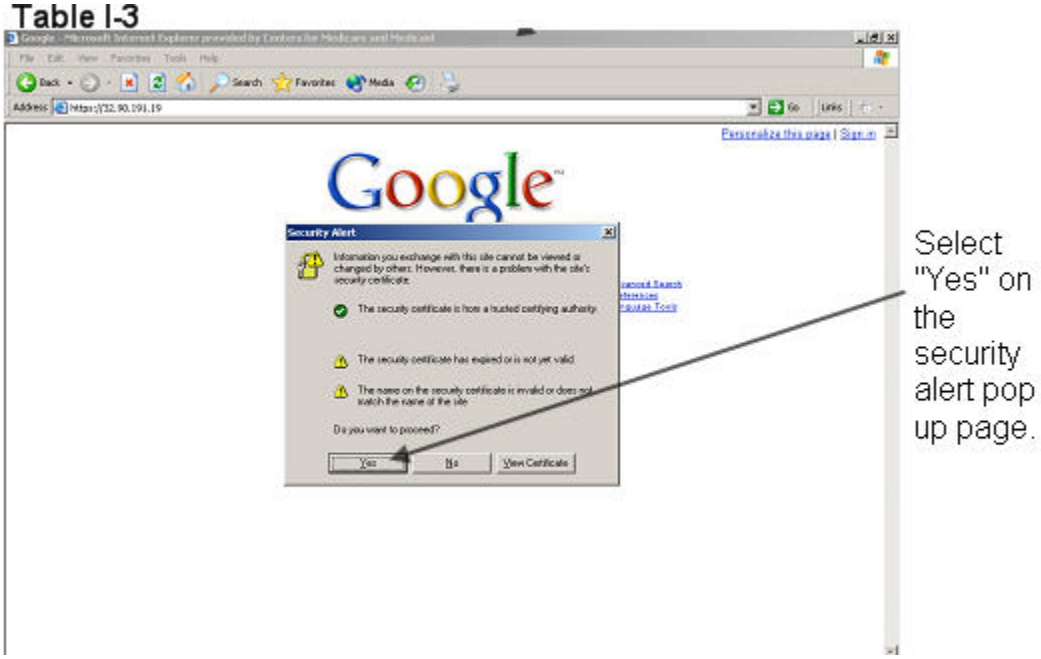
HOW TO ACCESS THE HPMS USING AN MDCN LEASE LINE

STEP 1

Open your web browser (e.g., Internet Explorer) and enter the CMS MDCN access address https://32.90.191.19 in the Address bar.

Select the "Yes" button on the Security Alert pop-up page. (Table I-3)

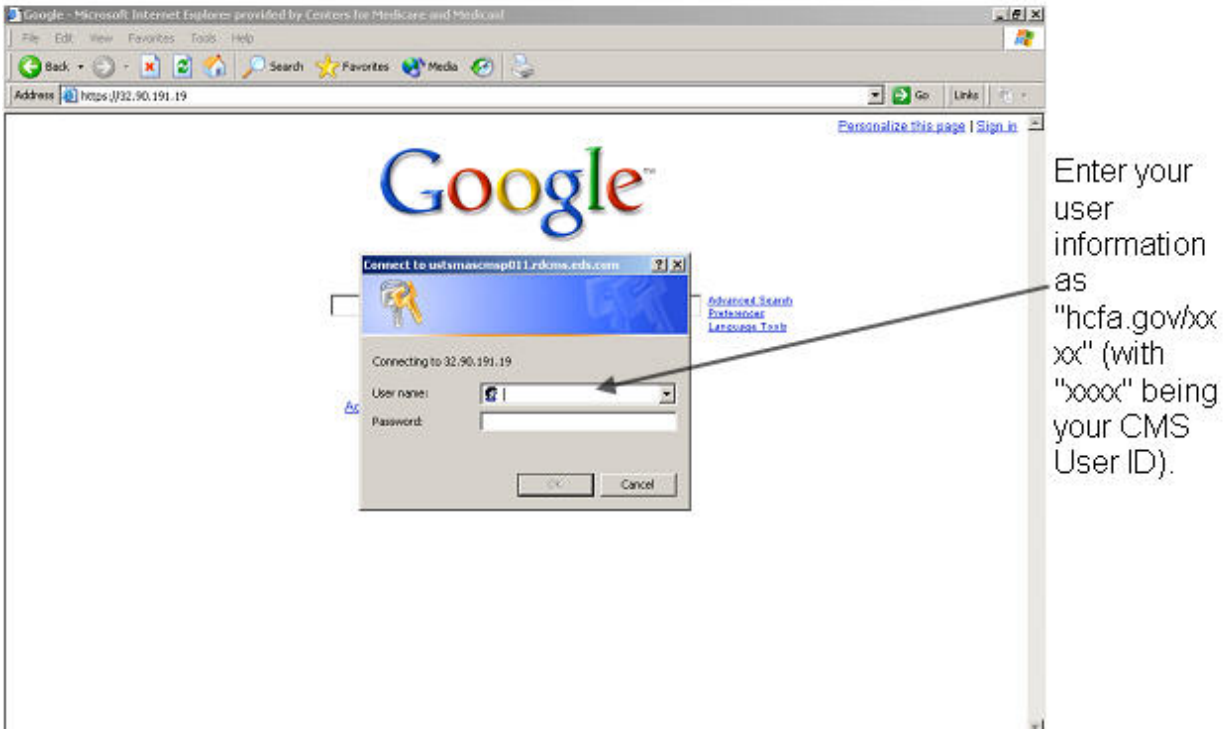
Table I-3



STEP 2

Enter your User Name as hcfa.gov/xxxx – where "xxxx" is your 4 character CMS User ID. Enter your password and select the "OK" button (Table I-4) to access the **HPMS Home Page.**

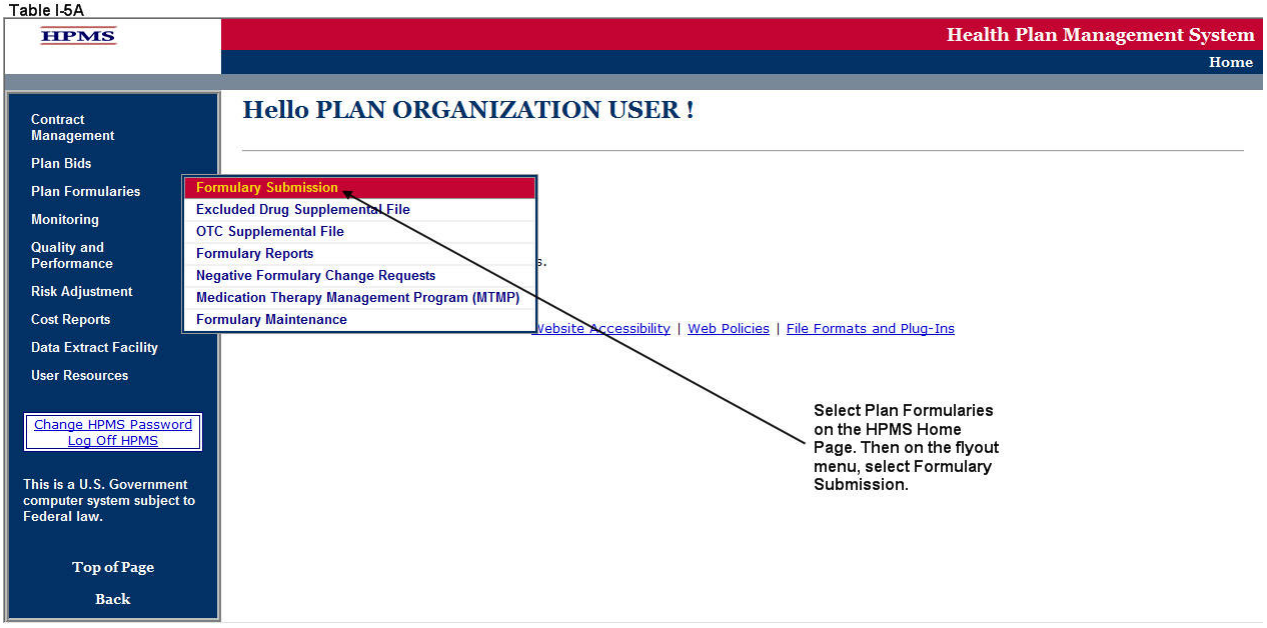
Table I-4



ACCESS THE HPMS FORMULARY SUBMISSION MODULE

To access the Formulary Submission Module, select **Plan Formularies** in the Left Navigation Bar of the HPMS Home Page. On the fly out menu, select **Formulary Submission** (see Table I-5A). This will take you to the Formulary Submission Contract Year Selection page.

Table I-5A



STEP 2

On the **Formulary Submission Contract Year Selection page,** select the appropriate contract year (see Table I-5B). This will take you to the **Formulary Submission Start page** (see Table I-5C).

Table I-5B

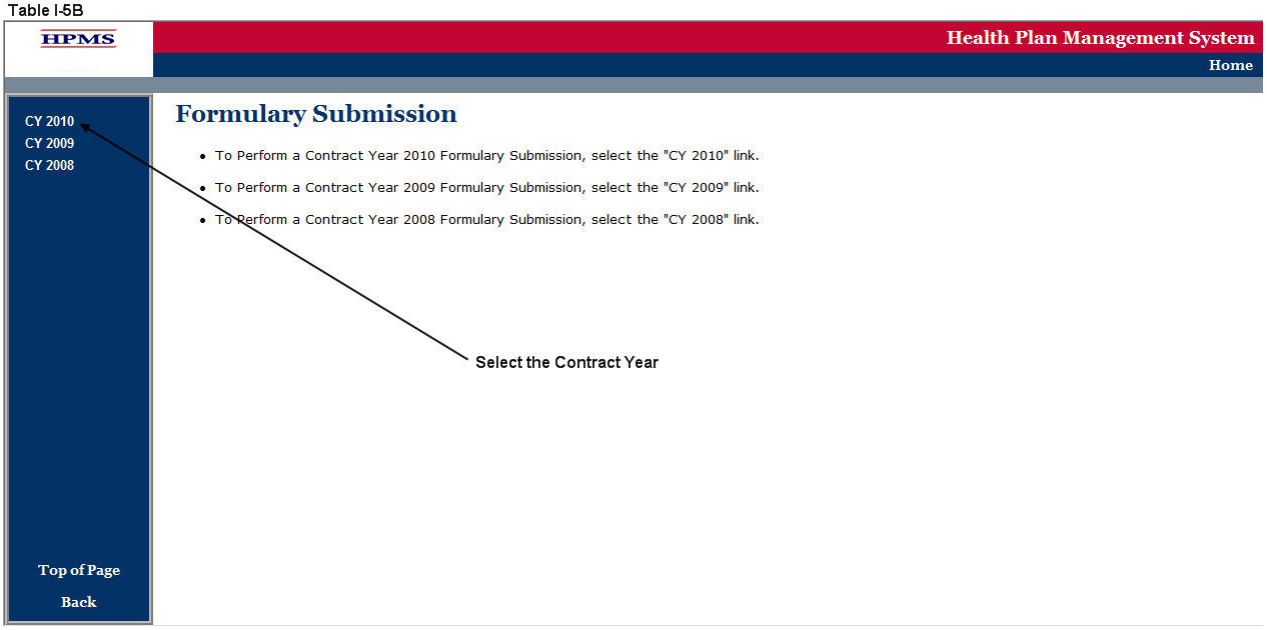
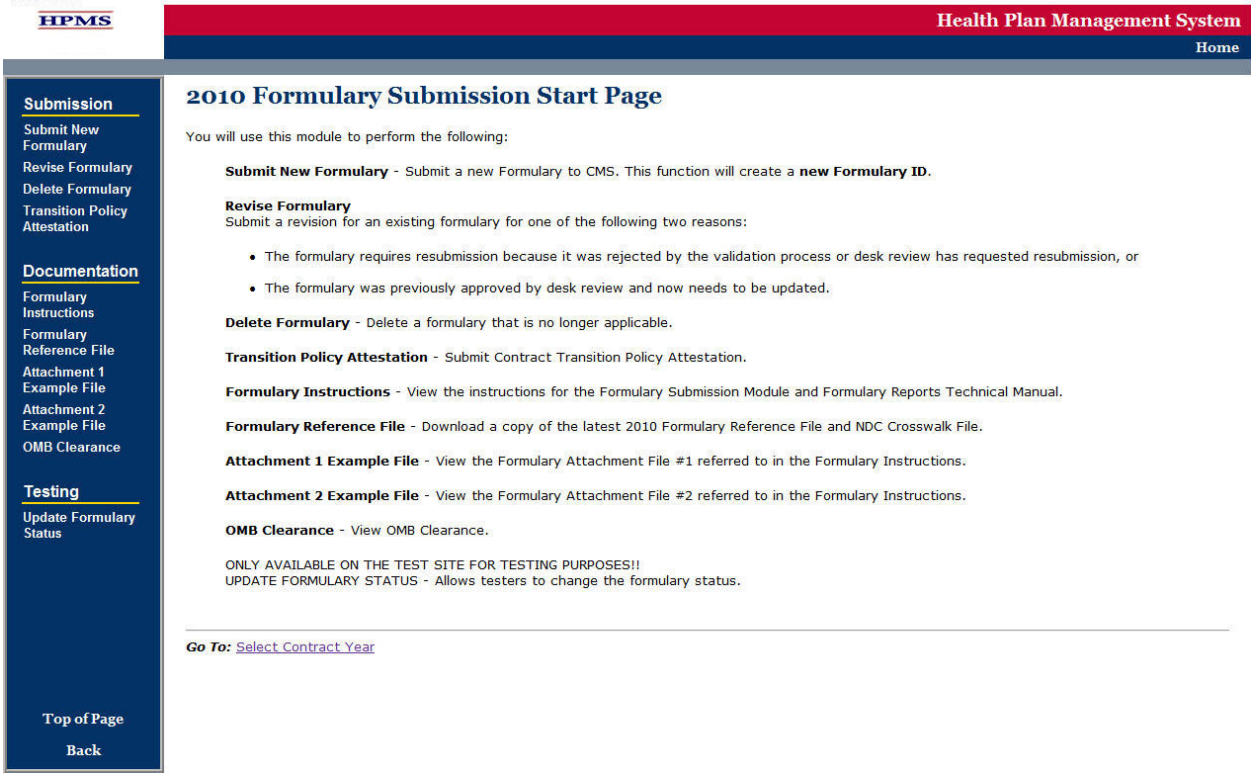


Table I-5C



BEFORE YOU BEGIN THE FORMULARY SUBMISSION PROCESS

The formulary submission process contains a series of web pages that will collect information from the submitter. **Prior to beginning the submission process, you must ensure that the Formulary Contact information in the Contract Management module is completed.** You

will not be able to submit a formulary for a contract that does not have this information. The Formulary Contact as well as the Formulary Upload Contact (the submitter) will receive all email notifications regarding the status of the formulary. Appendix D provides various validation rules for the formulary submission process.

II. How To Submit A New Formulary

The Submit New Formulary function is used to submit a new formulary. If you need to revise a formulary a previously submitted formulary, you should use the Revise Formulary function (refer to Chapter III).

When submitting a new formulary, you will:

1. **Associate Contracts to the Formulary** - Associate one or more of your contracts to the formulary submission.

2. **Provide Formulary Information** – Provide information about the formulary submissions including: Formulary Name; Formulary Classification System; Number of Tiers; Quantity Limit status; Limited Access status; Prior Authorization status; and Step Therapy status.

3. **Provide Formulary Tier Information** – Provide information about the tiers within the formulary.

4. **Upload Files** – Upload the Formulary File, Prior Authorization File, and Step Therapy File, if required.

5. **Verify the Submission** – Verify the correct information has been entered for your submission.

6. **Confirm the Submission** – Submit your formulary and obtain your assigned Formulary ID and confirmation your upload was successful.

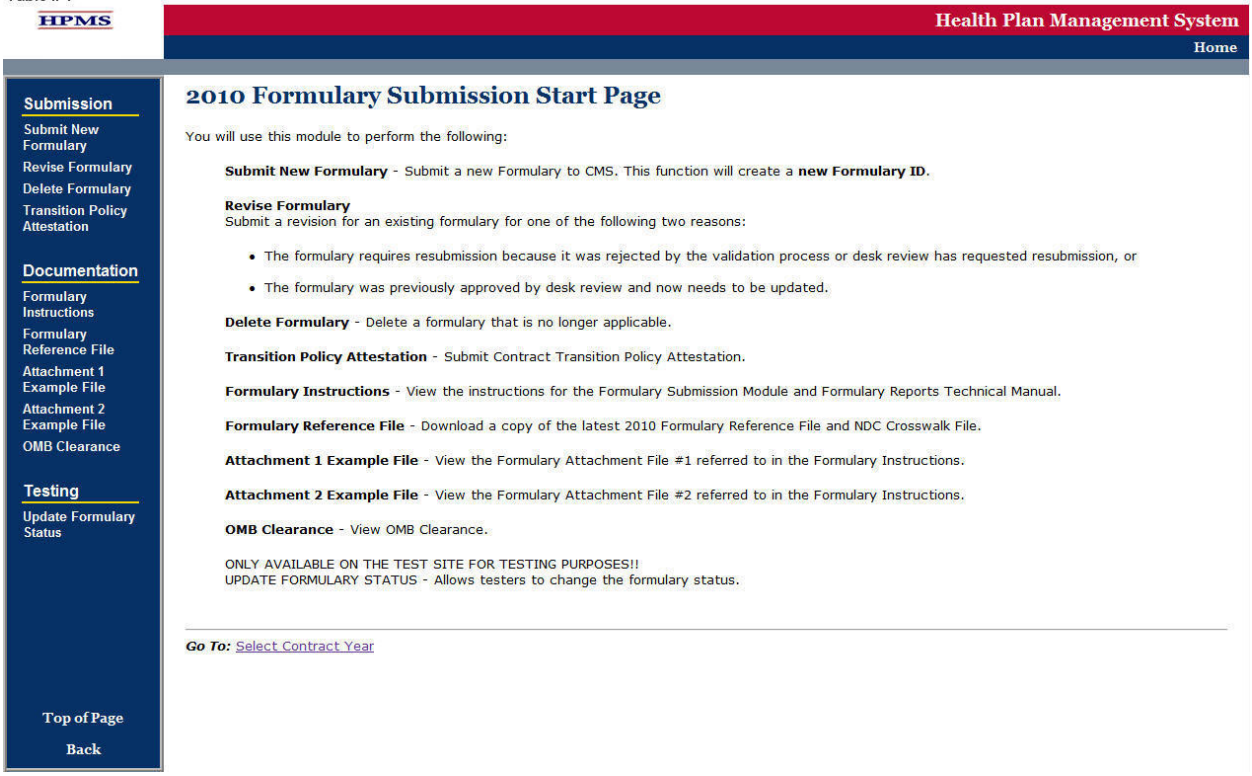
ASSOCIATE CONTRACTS TO FORMULARY

The **Associate Contracts to Formulary** page will allow you to associate one or more of your contracts to the formulary submission.

STEP 1

As shown in Table II-1, select **Submit New Formulary** from the **Formulary Submission Start Page.** (If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS formulary submission Module" in Chapter I). This will take you to the Associate Contracts to Formulary page.

Table II-1



STEP 2

On the **Associate Contracts to Formulary** page (Table II-2), select one or more of the contracts listed on the page to associate with the new formulary. If you cannot see one of your contracts, please refer to Section I – Getting Started. Also, review the formulary upload contact information listed at the bottom of the page to ensure your current email address is in HPMS.

STEP 3

Select the Next button to confirm the Contract Associations (Table II-2). This will take you to the Formulary Information page.

Table II-2

HPMS

Health Plan Management System

Home

Formulary Submission

Associate Contracts to Formulary

Select one or more contracts to associate with this formulary. If you are unable to select a contract because the Formulary Contact is unassigned or there is no email address, please go to the Contract Management Module to update this information.

NOTE: Prior to contract bid approval, the formulary/contract association can be updated by selecting or deselecting the checkbox beside a contract.

Contracts Associated with this Formulary			
Included	Contract Number	Contract Name	Formulary Contact
☐	Z0001	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0002	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0003	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0004	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0005	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0006	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0007	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0008	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0009	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0010	EXAMPLE CONTRACT	-- UNASSIGNED --

Please verify that your email address is correct. This email address will be used to communicate the status of this formulary submission. If you need to update your email address, please go to the User Account Maintenance Module and make this change before submitting your formulary information.

Formulary Upload Contact	
User ID:	0001
Name:	John Test
E-mail:	test@test.com

Select the contract(s) to associate with the formulary.

Review the formulary contact information to ensure it is correct.

Back Next

Click on the Next button.

Go To: Formulary Submission Start Page Select Contract Year

FORMULARY INFORMATION

The **Formulary Information** page collects information about your formulary submission including: Formulary Name; Formulary Classification System; Number of Tiers; Quantity Limit status; Limited Access status; Prior Authorization status; and Step Therapy status.

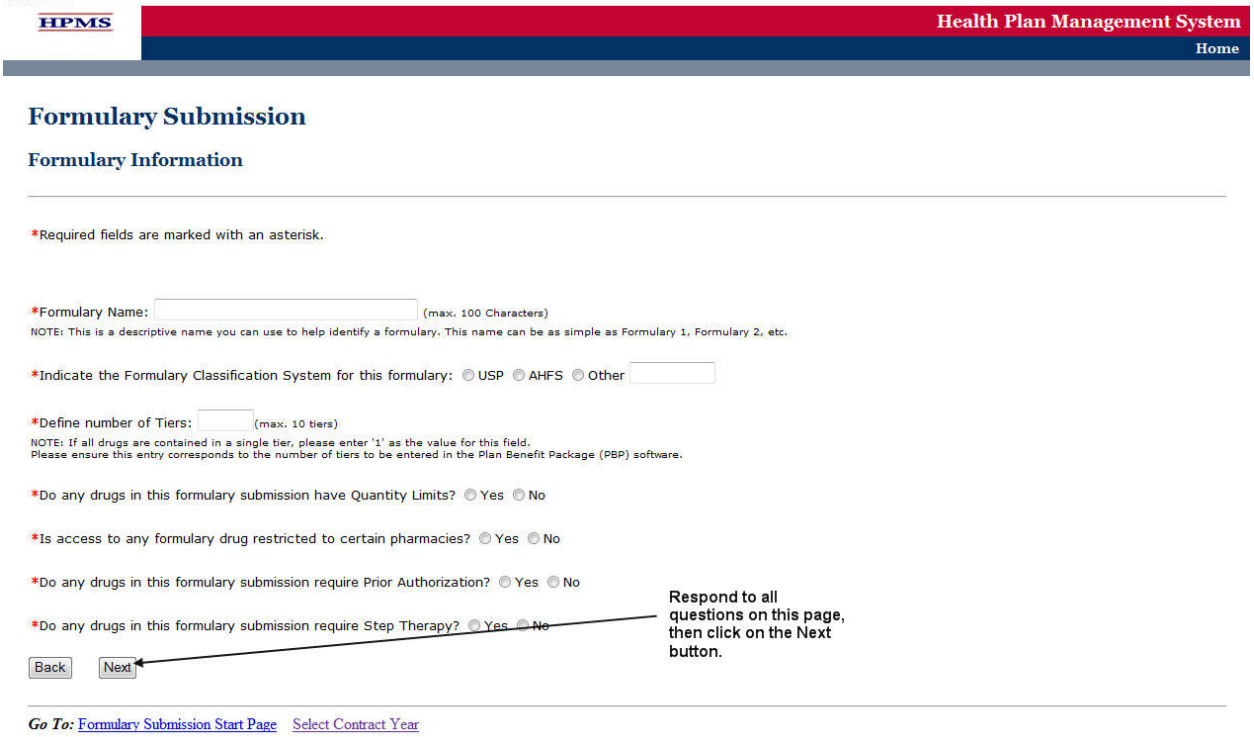
STEP 1

On the **Formulary Information** page (Table II-3), respond to all of the questions. All fields are required.

STEP 2

Select the Next button to confirm your entries and move to the Formulary Tier Information page.

Table II-3



FORMULARY TIER INFORMATION

The **Formulary Tier Information** page collects information about the tiers within the formulary. The page will automatically generate the number of tiers based on the information you entered on the prior (Formulary Information) page. The tier information that you enter in the formulary submission module must correspond to the number of tiers that will be identified in the corresponding CY 2010 PBP software.

When developing the formulary tier structure utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers

within the formulary structure should be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 should have a higher cost-share for beneficiaries than drugs in Tier 2.

STEP 1

On the **Formulary Tier Information** page (Table II-4) indicate the Anticipated Tier Name, Preferred Tier designation, Specialty Tier designation, and Drug Types for each tier.

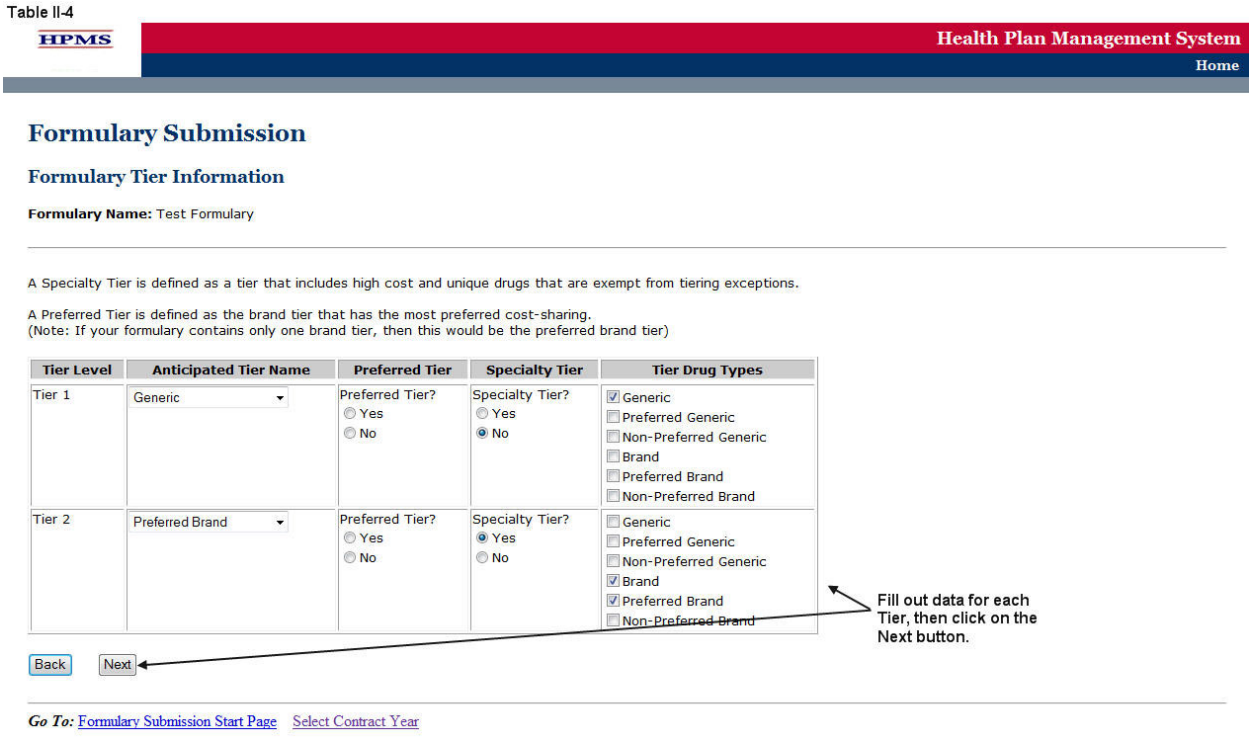
Keep in mind:

- **Anticipated Tier Name**: If you select "Other" as the Anticipated Tier Name, you must also enter data in the "Other Anticipated Tier Name" field that will appear when you select "Other."
- **Preferred Tier**: The brand tier that has the most preferred cost-sharing should be the "Preferred Tier." (Note: If your formulary contains only one brand tier, then this would be the preferred brand tier). If a tier is designated as the Preferred Tier, then it cannot also be designated as a Specialty Tier.
- **Specialty Tier:** Drugs within the Specialty Tier are exempt from tiering exceptions. You can only designate one formulary tier as a Specialty Tier, and you cannot designate the Preferred Tier as a Specialty Tier. In addition, you can only include drugs on a specialty tier if they meet the cost criteria outlined in the CY 2010 Call Letter.

STEP 2

Select the Next button to confirm your information and move to the Upload Files page.

Table II-4



UPLOAD FILES

The **Upload Files** page allows you to specify the Formulary File, Prior Authorization File, and Step Therapy File you want to upload. The page will pre-determine what you need to upload based on your responses on the Formulary Information and Formulary Tier Information pages.

It is imperative that the files you are uploading be in the following formats:

- **Formulary File** - ASCII Tab delimited text file, e.g. *formulary123*.txt

  For more information/assistance on the Formulary File layout, see Appendices A and B in this Manual and Attachment 1 Example File and Attachment 2 Example File available from the Formulary Submission module start page.

- **Prior Authorization File** – ASCII Tab delimited text file, e.g. *formularyPA*.txt

  For more information/assistance on the Prior Authorization File, see Appendix B.

- **Step Therapy File** – ASCII Tab delimited text file, e.g. *steptherapy123ST*.txt

  For more information/assistance on the Step Therapy File, see Appendix B.

STEP 1

On the **Upload Files** page (Table II-5), enter the full path and name of the Formulary Text File (Tab delimited .txt only) in the "Formulary File" field, e.g. c:\myformularyfile.txt. If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file.

STEP 2

Enter the full path and name of the Prior Authorization File (Tab delimited .txt file only) in the "Prior Authorization File" field or click on the "Browse" button to locate and attach the file. (Table II-5).

Note: If you selected "No" for the prior authorization question from the Formulary Information page this field will not be displayed.

STEP 3

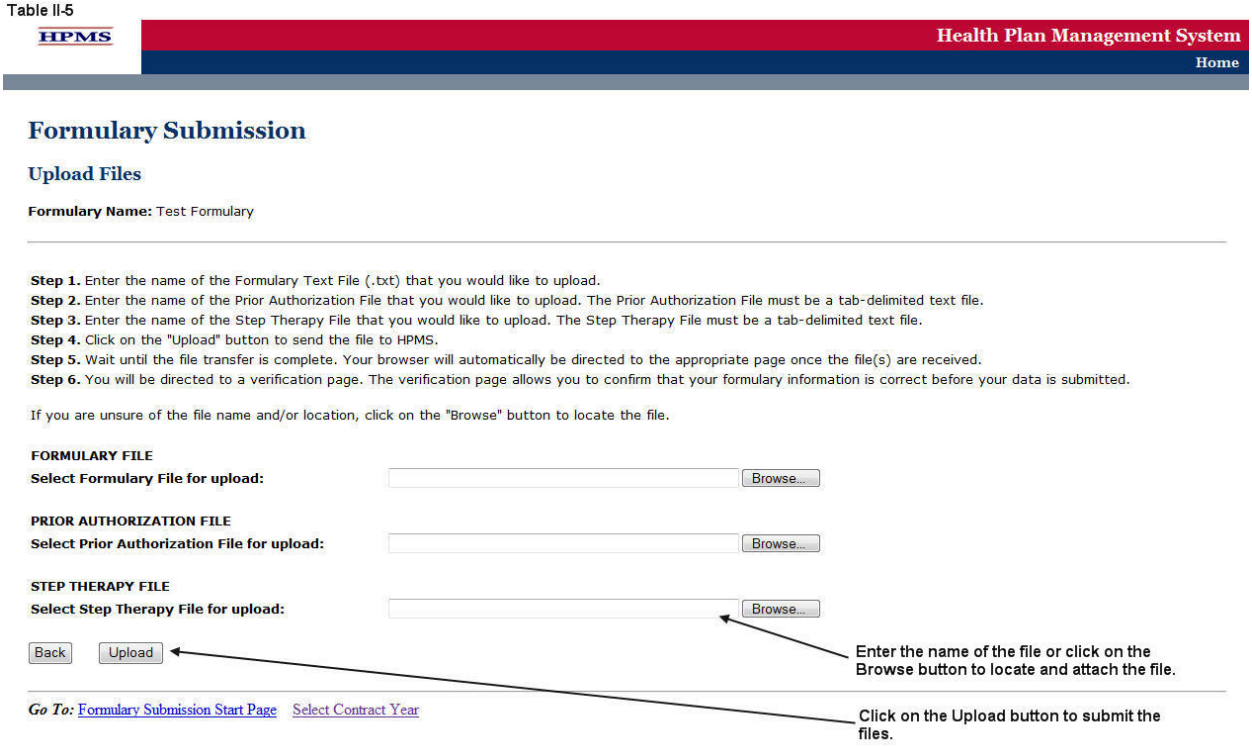
Enter the full path and name of the Step Therapy File (Tab delimited .txt file only) in the "Step Therapy File" field or click on the "Browse" button to locate and attach the file. (Table II-5).

Note: If you selected "No" for the step therapy question from the Formulary Information page this field will not be displayed.

STEP 4

Select the Upload button to prepare your files for submission to HPMS and to continue to the Verify Submission page. Please wait until the file transfer is complete before attempting to navigate further.

Table II-5



VERIFY SUBMISSION

The **Verify Submission** page allows you to verify the information you entered during the submission process before you complete the upload and submit the information to CMS.

STEP 1

On the **Verify Submission** page (Table II-6), review the information for accuracy.

STEP 2A

If any information is incorrect, select the Back button to correct the information as necessary.

STEP 2B

If all information is correct, select the Submit button to send the submission to CMS for review. This will take you to the Submission Confirmation page.

Table II-6

HPMS

Health Plan Management System

Home

Formulary Submission

Verify Submission

Please note that your data has not yet been submitted.

Formulary Name: Test Name
Formulary ID: 00000016
Formulary Version: 1

Please verify that the information entered is correct. Select the "Submit" button to submit your Formulary Information. If any information is incorrect, please select the "Back" button at the bottom of the page to correct your information.

Once your files have been uploaded, HPMS will send to you a confirmation email and you will also be directed to a Submission Confirmation page confirming the receipt of your upload. Depending on the size of your files, this may take some time. If you never receive any confirmation of your upload, please contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov.

Contract(s) Associated with Formulary: Z0001, Z0002, Z0003, Z0004

Contacts to be notified of this formulary submission			
	User ID	**Name**	**E-mail**
Upload User	Login1	John Test	test@test.com
Z0001	n/a	John Test	test@test.com
Z0002	n/a	John Test	test@test.com
Z0003	n/a	John Test	test@test.com
Z0004	n/a	John Test	test@test.com

Formulary Classification System used for this formulary: USP

Number of Tiers: 5

Tier Level	Anticipated Tier Name	Specialty Tier?	Tier Drug Types
1	Generic	YES	Brand
2	Generic	NO	Preferred Generic
3	Generic	NO	Non-Preferred Generic
4	Generic	NO	Preferred Brand
5	Generic	NO	Brand

Formulary includes drugs that have Quantity Limits? YES

Formulary includes drugs that have Pharmacy Restrictions? YES

Formulary includes drugs that require Prior Authorization? YES

Formulary includes drugs that require Step Therapy? YES

Files to be Uploaded	
Title	**File Name**
Formulary File	C:\Documents and Settings\text.txt
Prior Authorization File	C:\Documents and Settings\text.txt
Step Therapy File	C:\Documents and Settings\text.doc

If any information is incorrect, select the Back button to correct it. Otherwise, select the Submit button.

Back Submit

Go To: Formulary Submission Start Page Select Contract Year

SUBMISSION CONFIRMATION

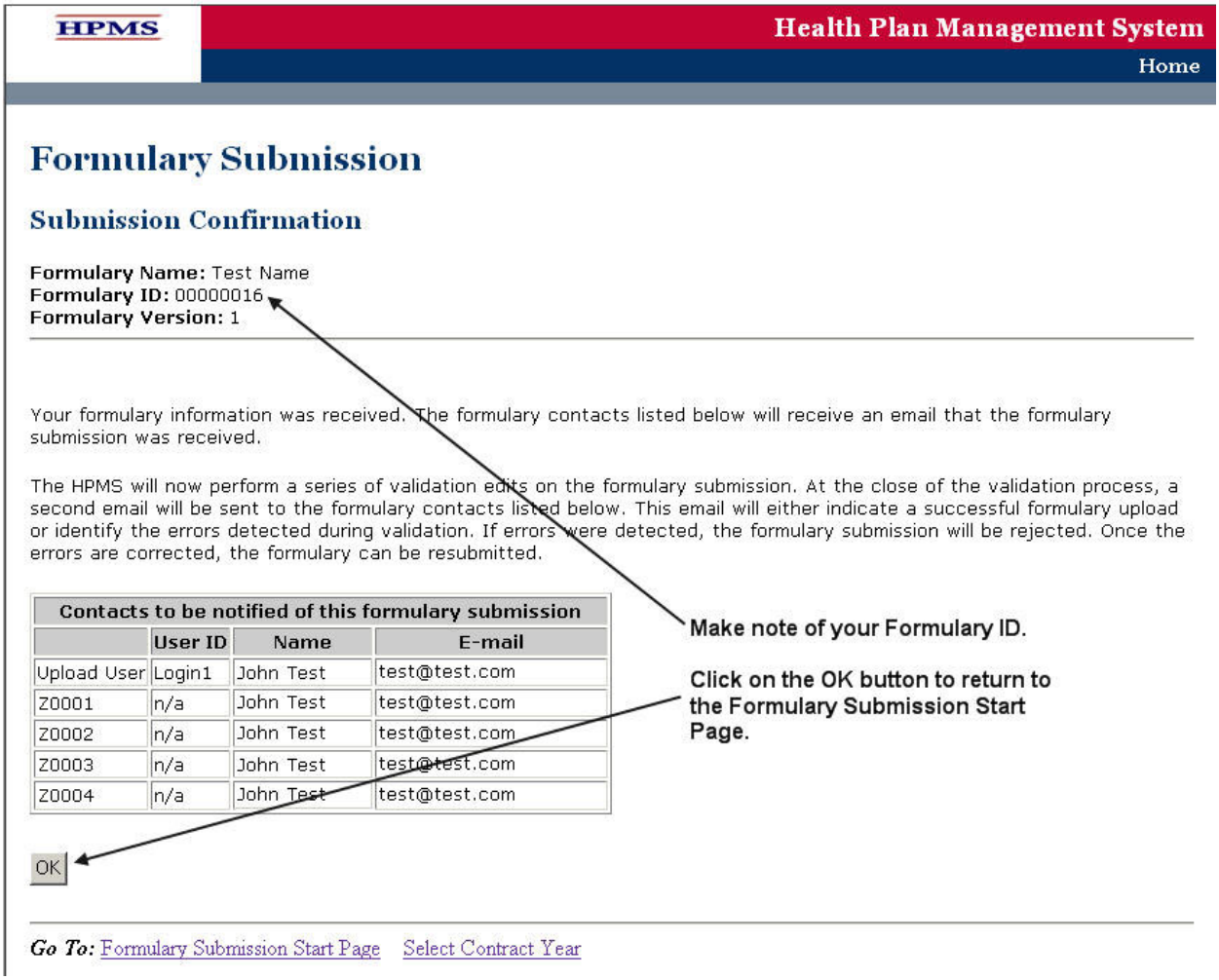
The **Submission Confirmation** page confirms successful receipt of your submission and provides the unique Formulary ID assigned to your submission. This page will also generate an email to both the Formulary Contract and the Formulary Upload Contact identified on this page acknowledging receipt of the submission and the assigned Formulary ID.

Important: You should make note of the Formulary ID. You will need this ID for all subsequent resubmissions.

STEP 1

On the **Submission Confirmation** page (Table II-7) review the information. As explained above, **MAKE NOTE OF YOUR ASSIGNED FORMULARY ID**.

Table II-7



STEP 2

Select the OK button to return to the Formulary Submission Start Page.

At this point, you have finished submitting your new formulary and need to wait for an email regarding the status of your submission. After receiving your submission the HPMS will perform

a series of validation edits. At the close of the validation process, a follow-up e-mail will be sent to the designated formulary contacts. This e-mail will either indicate that the formulary was successfully validated or it will identify errors detected during the validation process. If errors were detected, the formulary submission will be rejected. The email will list a maximum of 200 error messages. You must correct the formulary and resubmit using your assigned formulary ID and the Revise Formulary function (see Chapter III).

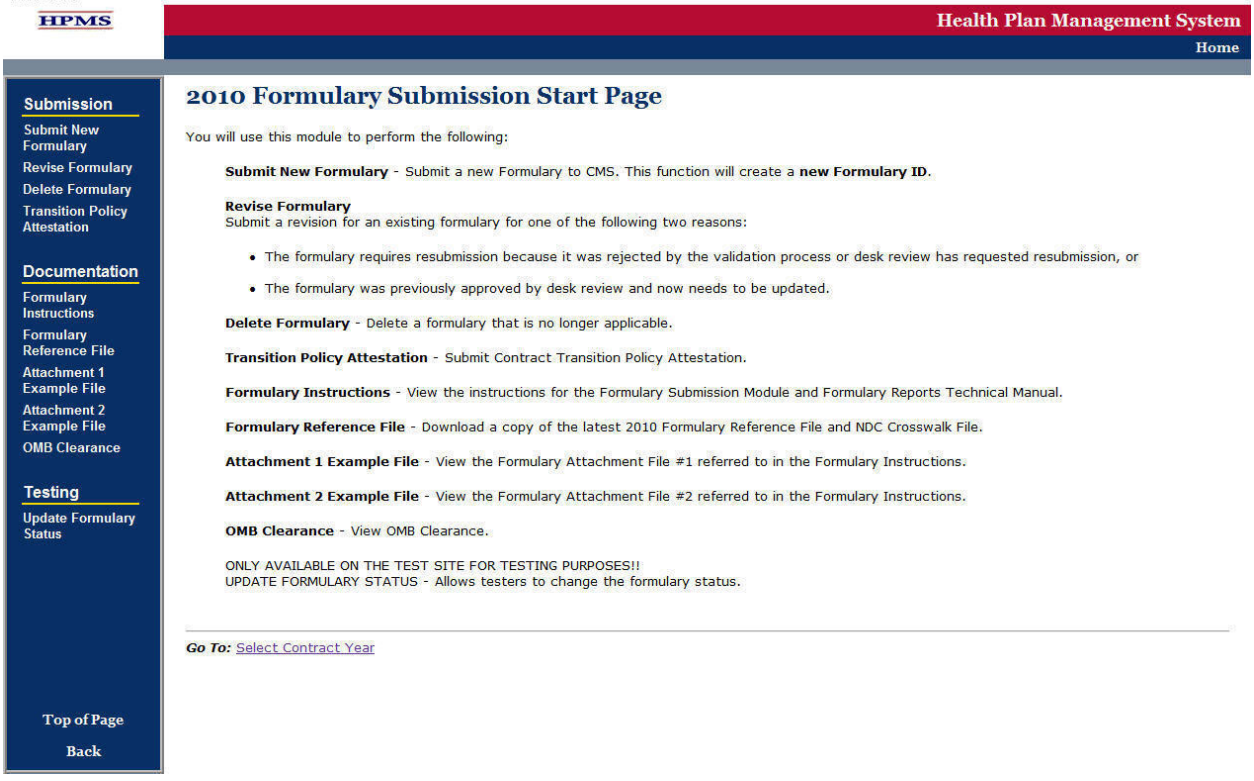
III. How To Revise A Formulary (Resubmissions)

The **Revise Formulary** functionality is used to update formularies that have already been submitted to CMS via the HPMS. You are only permitted to update a formulary during scheduled update windows and/or when a formulary has a status of "Resubmission Requested" or "Rejected by Validation" (see "How to Determine Formulary Submission Status" below). Formularies that are "Approved" may only be updated during the assigned update windows.

DETERMINE YOUR FORMULARY SUBMISSION STATUS

As shown in Table III-1, select **Revise Formulary** from the **Formulary Submission Start Page.** (If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS formulary submission Module" in Chapter I). This will take you to the Formulary Resubmission-Select a Formulary page.

Table III-1

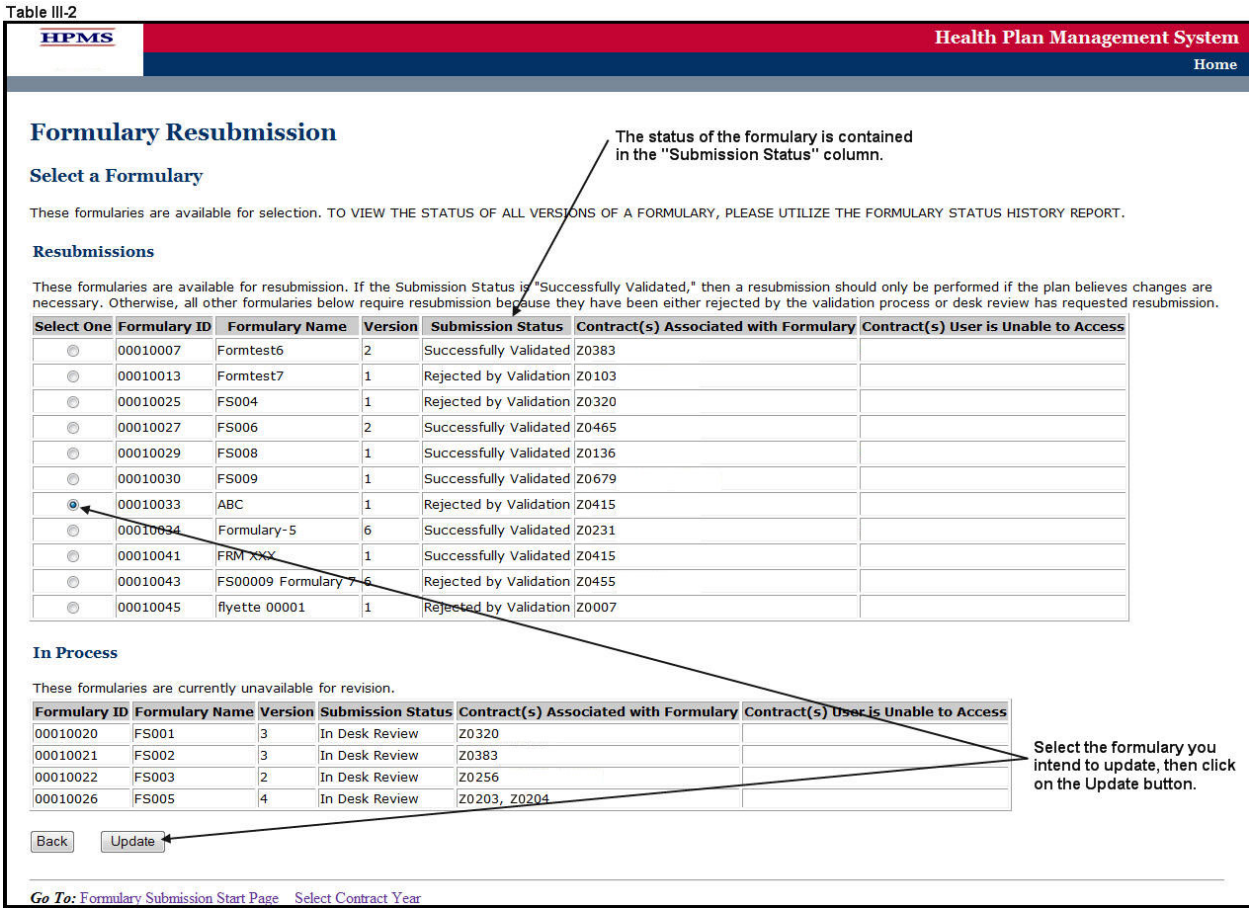


The **Formulary Resubmission–Select a Formulary** page (Table III-2) groups formularies into three categories:

- Resubmission – Formularies that are eligible for resubmission either due to a validation failure or because a reviewer requested a resubmission.
- Updates – Formularies that are approved by CMS and are available for update. This group also includes formularies eligible for resubmission during a scheduled window.
- In Process – Formularies that are in desk review.

Within each category is a table listing information about each formulary. This table includes a column entitled "Submission Status." As noted above, you can only update formularies that have a submission status of "**Resubmission Requested**" or "**Rejected by Validation.**" You can update formularies that are "**Approved**" during the assigned update windows. Note: In the event CMS conducts a "mass gate opening," formularies eligible for resubmission during the gate opening will show an "Approved" status.

Table III-2



REVISE A FORMULARY

STEP 1

As shown in Table III-1, select Revise Formulary from the **Formulary Submission Start Page.** (If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS formulary submission Module" in Chapter I). This will take you to the Formulary Resubmission - Select a Formulary page.

STEP 2

On the **Formulary Resubmission - Select A Formulary** page (Table III-2), select the formulary you wish to update. Then click on the Update button. This will take you to the Formulary Resubmission - Associate Contracts to Formulary page.

ASSOCIATE CONTRACTS TO FORMULARY

The **Formulary Resubmission - Associate Contracts to Formulary** page (Table III-3) will allow you to associate one or more of your contracts to the formulary resubmission.

Note: When revising a formulary, you cannot add or remove a contract from a formulary association after the CMS-specified due date.

STEP 1

On the **Formulary Resubmission - Associate Contracts to Formulary** page (Table III-3), select one or more of the contracts listed on the page to associate with the formulary.

STEP 2

On the **Formulary Resubmission - Associate Contracts to Formulary** page select the Next button to confirm the Contract Associations (Table III-3). This will take you to the Formulary Resubmission - Formulary Information page.

Table III3

HPMS

Health Plan Management System

Home

Formulary Resubmission

Associate Contracts to Formulary

Formulary Name: EXAMPLE CONTRACT
Formulary ID: 00010011
Formulary Version: 2

Select one or more contracts to associate with this formulary. If you are unable to select a contract because the Formulary Contact is unassigned or there is no email address, please go to the Contract Management Module to update this information.

Contracts Associated with this Formulary			
Included	Contract Number	Contract Name	Formulary Contact
☐	Z0115	EXAMPLE CONTRACT	-- UNASSIGNED --
☑	Z0182	EXAMPLE CONTRACT	John Test test@test.com
☐	Z0383	EXAMPLE CONTRACT	John Test test@test.com
☐	Z0419	EXAMPLE CONTRACT	John Test test@test.com
☐	Z0702	EXAMPLE CONTRACT	John Test test@test.com
☐	Z0051	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0219	EXAMPLE CONTRACT	John Test test@test.com
☐	Z0289	EXAMPLE CONTRACT	-- UNASSIGNED --
☐	Z0335	EXAMPLE CONTRACT	-- UNASSIGNED --

Please verify that your email address is correct. This email address will be used to communicate the status of this formulary submission. If you need to update your email address, please go to the User Account Maintenance Module and make this change before submitting your formulary information.

Formulary Upload Contact	
User ID:	jkS0
Name:	John Test
E-mail:	test@test.com

Back Next

Go To: Formulary Submission Start Page Select Contract Year

FORMULARY INFORMATION

The **Formulary Resubmission - Formulary Information** page collects information about your formulary resubmissions including: Formulary Name; Formulary Classification System; Number of Tiers; Quantity Limit status; Limited Access status; Prior Authorization status; and Step Therapy status.

Note: If a prior version of the formulary has ever been Approved, you may not change the following fields on the Formulary Information page when resubmitting the formulary:

- Formulary Classification System, and
- Number of Tiers.

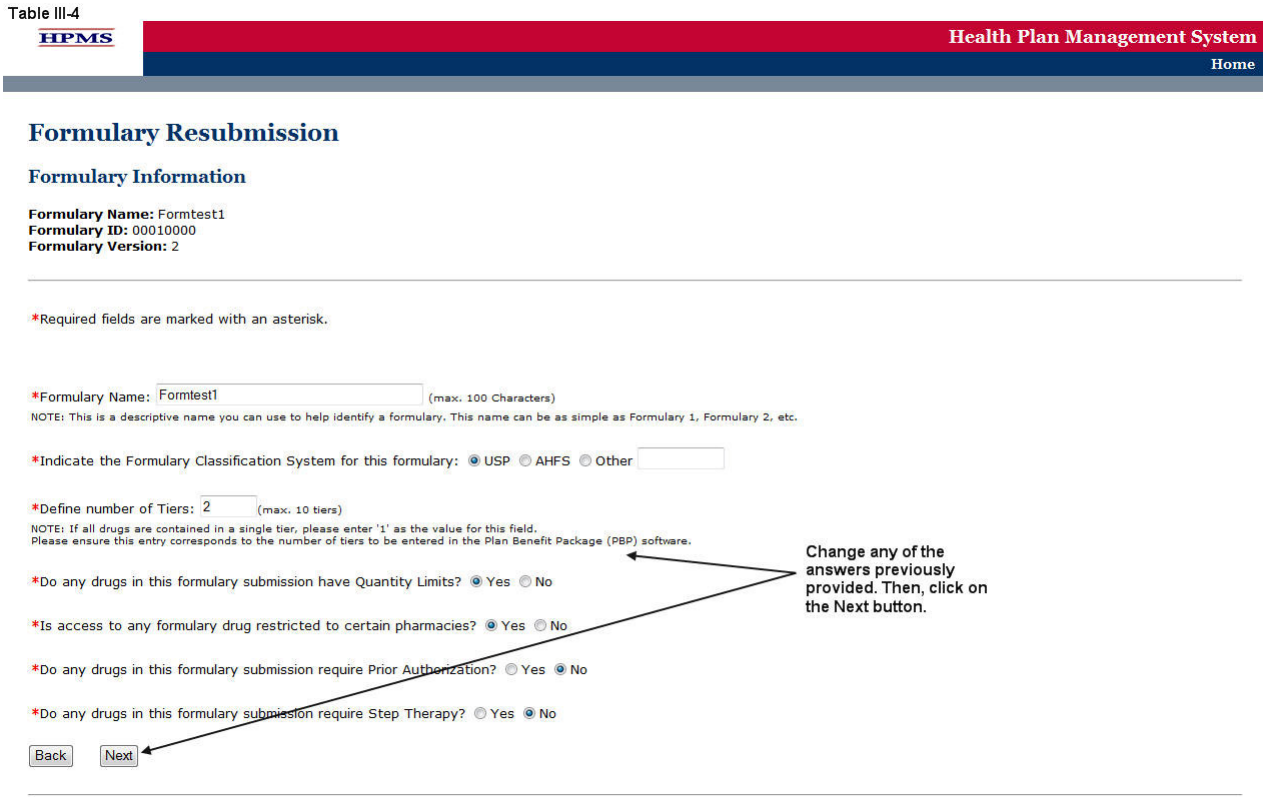
STEP 1

On the **Formulary Resubmission - Formulary Information** page (Table III-4), enter any changes to the answers previously provided.

STEP 2

Select the Next button to confirm your changes and move to the Formulary Resubmission - Formulary Tier Information page.

Table III-4



FORMULARY TIER INFORMATION

The **Formulary Resubmission - Formulary Tier Information** page collects information about the tiers within the formulary. **Note:** The system will not allow you to change the information on the Formulary Tier Information page once the formulary has been in Approved status.

STEP 1

On the **Formulary Resubmission - Formulary Tier Information** page (Table III-5), for each tier indicate the Anticipated Tier Name, Specialty Tier designation, and Drug Types.

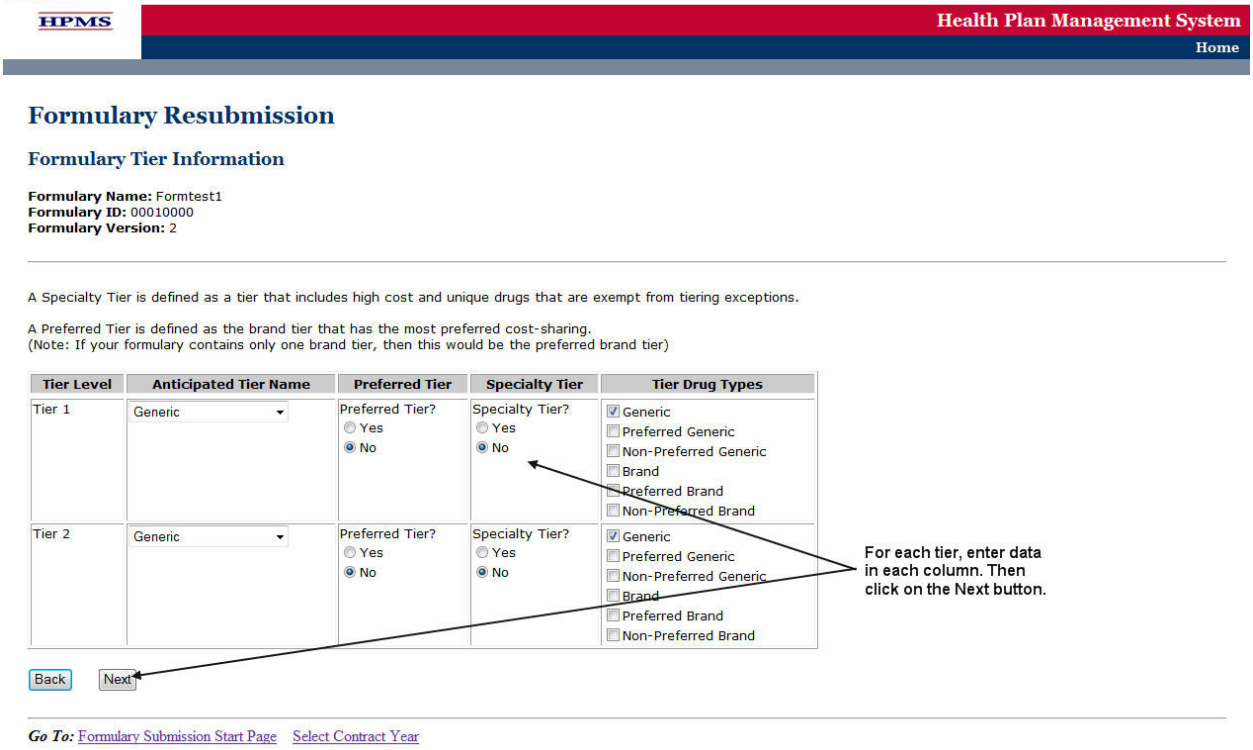
Keep in mind:

- **Anticipated Tier Name**: If you select "Other" as the Anticipated Tier Name, you must also enter data in the "Other Anticipated Tier Name" field that will appear once you select "Other."
- **Preferred Tier**: The brand tier that has the most preferred cost-sharing should be the "Preferred Tier." (Note: If your formulary contains only one brand tier, then this would be the preferred brand tier). If a tier is designated as the Preferred Tier, then it cannot also be designated as a Specialty Tier.
- **Specialty Tier:** Drugs within the Specialty Tier are exempt from "tiering" exceptions. You can only designate one formulary tier as a Specialty Tier, and you cannot designate the Preferred Tier as a Specialty Tier. In addition, you can only include drugs on a specialty tier if they meet the cost criteria outlined in the CY 2010 Call Letter.

STEP 2

Select the Next button to confirm your information and move to the Formulary Resubmission - Upload Files page.

Table III-5



UPLOAD FILES

The **Formulary Resubmission - Upload Files** page allows you to re-upload the Formulary File, Prior Authorization File, and Step Therapy File, if required. The page will determine what needs to be uploaded based on your prior responses on the Formulary Information and Formulary Tier Information pages.

It is imperative that the files you are uploading be in the following formats:

- **Formulary File** - ASCII Tab delimited text file, e.g. *formulary123*.txt

  For more information/assistance on the Formulary File layout, see Appendices A and B in this Manual and Attachment 1 Example File and Attachment 2 Example File available from the Formulary Submission Module Start Page).

- **Prior Authorization File** – ASCII Tab delimited text file, e.g. *formularyPA*.txt

  For more information/assistance on the Prior Authorization File, see Appendix B.

- **Step Therapy File** – ASCII Tab delimited text file, e.g. *steptherapy123ST*.txt

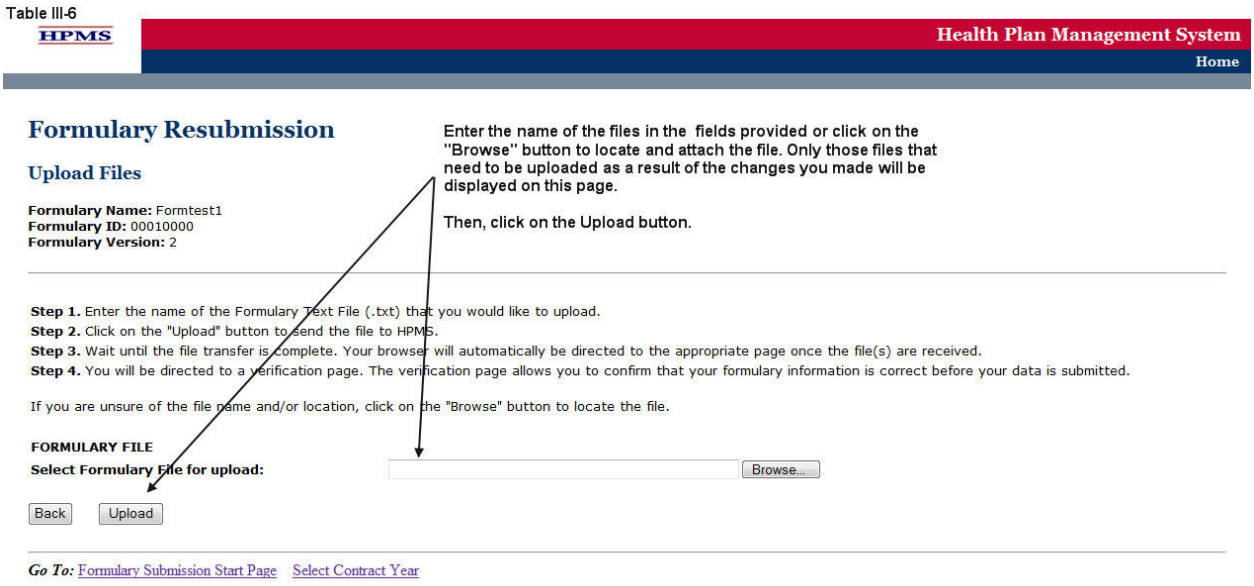
  For more information/assistance on the Step Therapy File, see Appendix B.

STEP 1

On the **Formulary Resubmission - Upload Files** page (Table III-6), enter the name of the files (Tab delimited .txt only) in the fields provided. (Only those files that need to be uploaded as a result of the changes you made will be displayed on this page.) If you are unsure of the file name and/or location, click on the "Browse" button to locate and attach the file.

STEP 2

Select the Upload button to prepare your files for submission to HPMS and to continue to the Formulary Resubmission - Verify Resubmission page. Please wait until the file transfer is complete before attempting to navigate further.



VERIFY RESUBMISSION

The **Formulary Resubmission - Verify Resubmission** page allows you to verify the information you entered during the resubmission process before you complete the upload and resubmit the information to CMS.

STEP 1

On the **Formulary Resubmission - Verify Resubmission** page (Table III-7), review the information for accuracy.

STEP 2A

If any information is incorrect, select the Back button to correct the information as necessary by returning to the appropriate pages.

STEP 2B

If all information is correct, select the Submit button to send the resubmission to CMS for review. This will take you to the Formulary Resubmission - Resubmission Confirmation page.

Table III-7

HPMS

Health Plan Management System

Home

Formulary Submission

Verify Submission

Please note that your data has not yet been submitted.

Formulary Name: Test Name
Formulary ID: 00000016
Formulary Version: 1

Please verify that the information entered is correct. Select the "Submit" button to submit your Formulary Information. If any information is incorrect, please select the "Back" button at the bottom of the page to correct your information.

Once your files have been uploaded, HPMS will send to you a confirmation email and you will also be directed to a Submission Confirmation page confirming the receipt of your upload. Depending on the size of your files, this may take some time. If you never receive any confirmation of your upload, please contact the HPMS Help Desk at either 1-800-220-2028 or hpms@cms.hhs.gov.

Contract(s) Associated with Formulary: X0001, X0002, X0003, X0004

Contacts to be notified of this formulary submission			
	User ID	**Name**	**E-mail**
Upload User	Login1	John Test	test@test.com
Z0001	n/a	John Test	test@test.com
Z0002	n/a	John Test	test@test.com
Z0003	n/a	John Test	test@test.com
Z0004	n/a	John Test	test@test.com

Formulary Classification System used for this formulary: USP

Number of Tiers: 5

Tier Level	Anticipated Tier Name	Specialty Tier?	Tier Drug Types
1	Generic	YES	Brand
2	Generic	NO	Preferred Generic
3	Generic	NO	Non-Preferred Generic
4	Generic	NO	Preferred Brand
5	Generic	NO	Brand

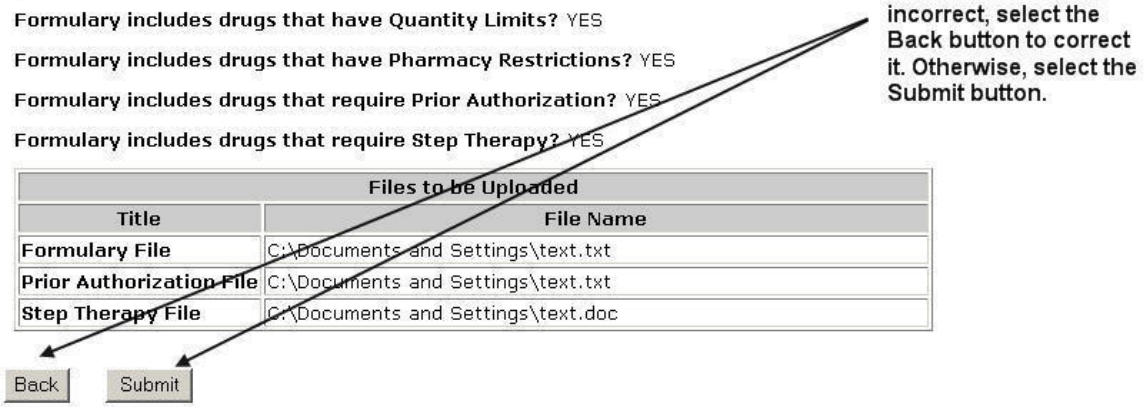
Formulary includes drugs that have Quantity Limits? YES

Formulary includes drugs that have Pharmacy Restrictions? YES

Formulary includes drugs that require Prior Authorization? YES

Formulary includes drugs that require Step Therapy? YES

Files to be Uploaded	
Title	**File Name**
Formulary File	C:\Documents and Settings\text.txt
Prior Authorization File	C:\Documents and Settings\text.txt
Step Therapy File	C:\Documents and Settings\text.doc



Back Submit

Go To: Formulary Submission Start Page Select Contract Year

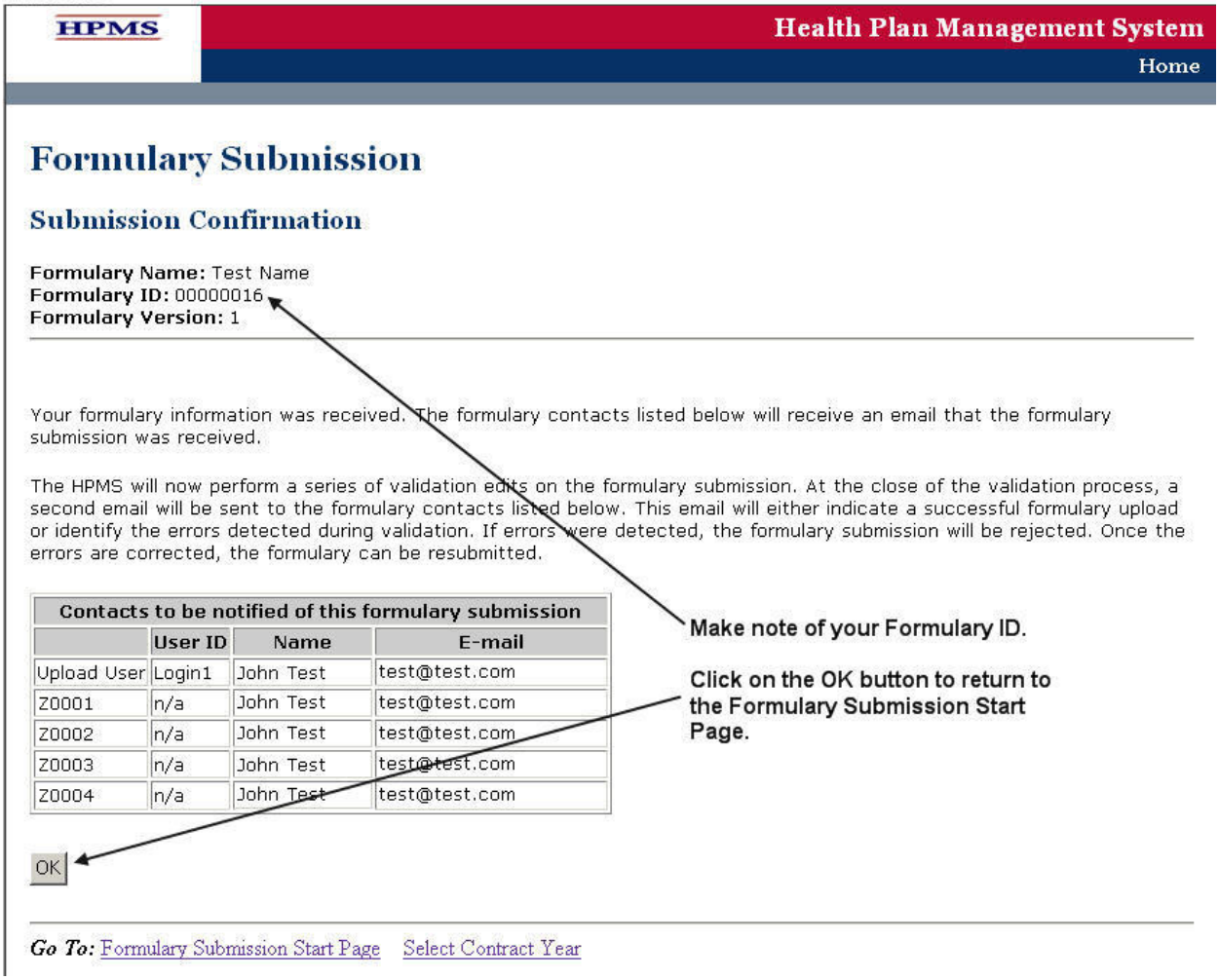
RESUBMISSION CONFIRMATION

The **Formulary Resubmission - Resubmission Confirmation** page provides a status of the successful upload. This page will also generate an email to both the Formulary Contract and the Formulary Upload Contact identified on this page acknowledging receipt of the resubmission.

On the **Formulary Resubmission - Resubmission Confirmation** page (Table III-8) review the information. Select the OK button to return to the Formulary Submission Start Page.

At this point, you have finished resubmitting your new formulary and need to wait for an email regarding the status of your resubmission. After receiving the uploaded formulary file the HPMS will perform a series of validation edits. At the close of the validation process, a follow-up e-mail will be sent to the designated formulary contacts. This e-mail will either indicate that the formulary was successfully validated or it will identify errors detected during the validation process. If errors were detected, the formulary resubmission will be rejected. The email will list a maximum of 200 error messages.

Table III-8



IV. How To Delete A Formulary

The **Delete Formulary** functionality allows you to delete existing formularies that have never been approved. You should only delete a formulary if you are certain that it is obsolete.

HOW TO DETERMINE WHICH FORMULARIES ARE ELIGIBLE FOR DELETION

As shown in Table IV-1, select Delete Formulary from the **Formulary Submission Start Page.** (If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS formulary submission Module" in Chapter I). This will take you to the Delete a Formulary Submission-Select a Formulary page.

The Delete a Formulary Submission-Select a Formulary page (Table IV-2) groups formularies into three categories:

- Resubmissions –Available for deletion - Formularies that are eligible for deletion.
- Approved Formularies – Unavailable for deletion – Formularies that are approved by CMS and that are not eligible for deletion.
- In Process – Formularies that are approved, in desk review, or uploaded but not yet processed

As noted above, you can only delete formularies in the "Resubmission – Available for Deletion" category.

Table IV-1

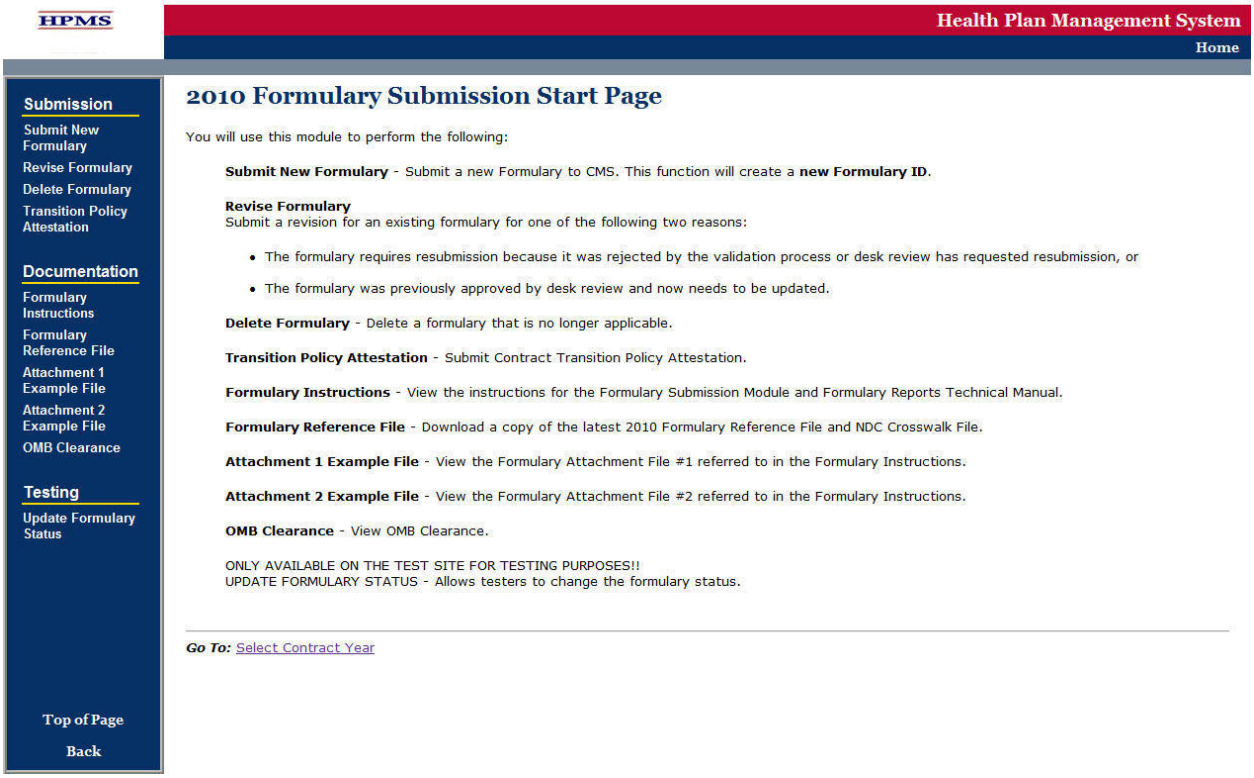
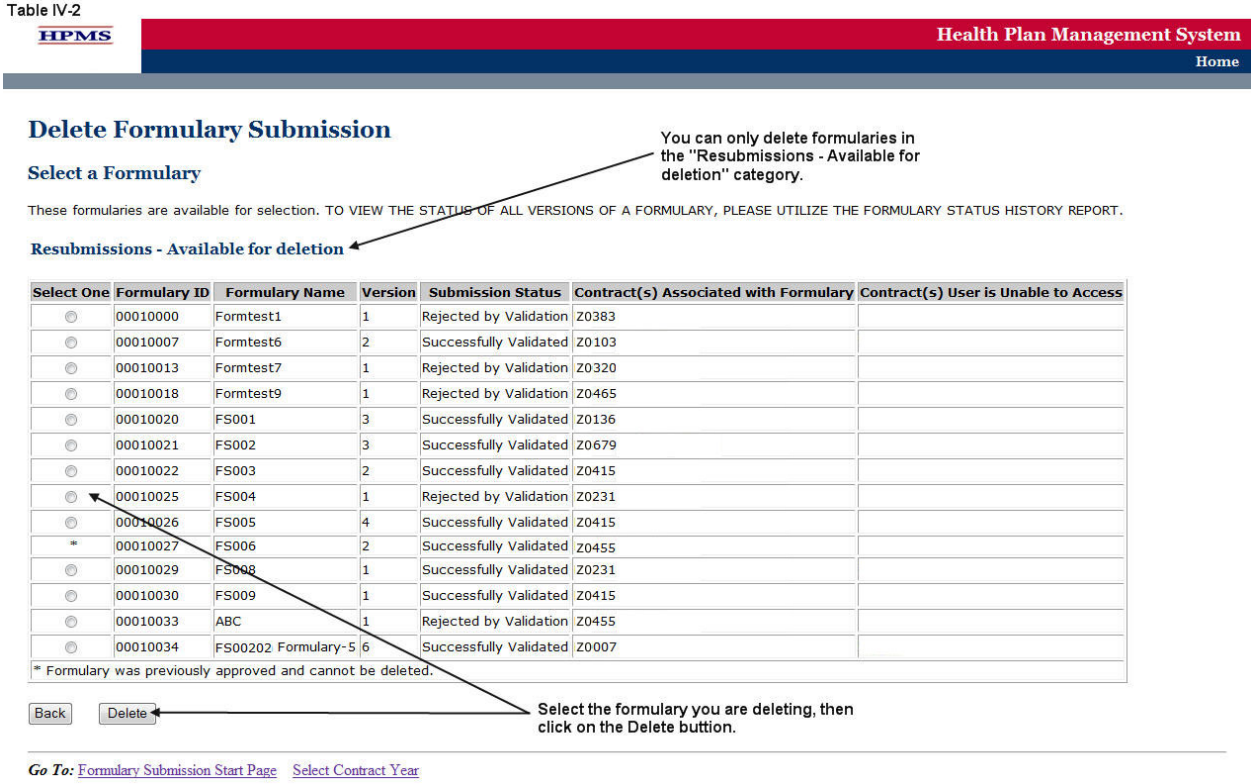

HPMS
Health Plan Management System
Home
Submission
Submit New Formulary
Revise Formulary
Delete Formulary
Transition Policy Attestation
Documentation
Formulary Instructions
Formulary Reference File
Attachment 1 Example File
Attachment 2 Example File
OMB Clearance
Testing
Update Formulary Status
Top of Page
Back
2010 Formulary Submission Start Page
You will use this module to perform the following:
Submit New Formulary - Submit a new Formulary to CMS. This function will create a new Formulary ID.
Revise Formulary
Submit a revision for an existing formulary for one of the following two reasons:
The formulary requires resubmission because it was rejected by the validation process or desk review has requested resubmission, or
The formulary was previously approved by desk review and now needs to be updated.
Delete Formulary - Delete a formulary that is no longer applicable.
Transition Policy Attestation - Submit Contract Transition Policy Attestation.
Formulary Instructions - View the instructions for the Formulary Submission Module and Formulary Reports Technical Manual.
Formulary Reference File - Download a copy of the latest 2010 Formulary Reference File and NDC Crosswalk File.
Attachment 1 Example File - View the Formulary Attachment File #1 referred to in the Formulary Instructions.
Attachment 2 Example File - View the Formulary Attachment File #2 referred to in the Formulary Instructions.
OMB Clearance - View OMB Clearance.
ONLY AVAILABLE ON THE TEST SITE FOR TESTING PURPOSES!!
UPDATE FORMULARY STATUS - Allows testers to change the formulary status.
Go To: Select Contract Year

Table IV-2



DELETE A FORMULARY

STEP 1

As shown in Table IV-1, select Delete Formulary from the **Formulary Submission Start Page.** (If you need help getting to the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS formulary submission Module" in Chapter I). This will take you to the Delete a Formulary Submission-Select a Formulary page.

STEP 2

On the **Delete a Formulary Submission-Select a Formulary** page (Table IV-2), select the formulary you wish to delete.

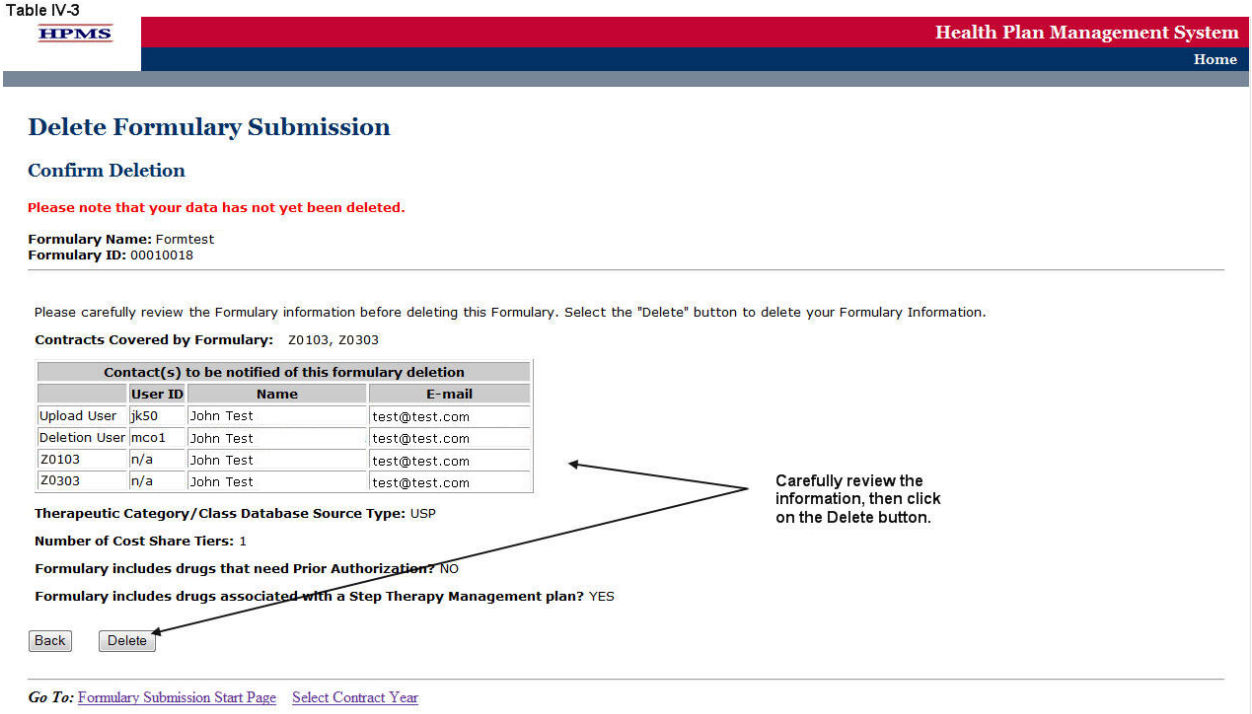
STEP 3

Click the Delete button (Table IV-2). This will take you to the Delete a Formulary Submission - Confirm Deletion page.

STEP 4

On the **Delete a Formulary Submission - Confirm Deletion** page (Table IV-3), review the page carefully and select the Delete button to finalize the deletion. This will take you to the Delete a Formulary Submission - Deletion Confirmation page.

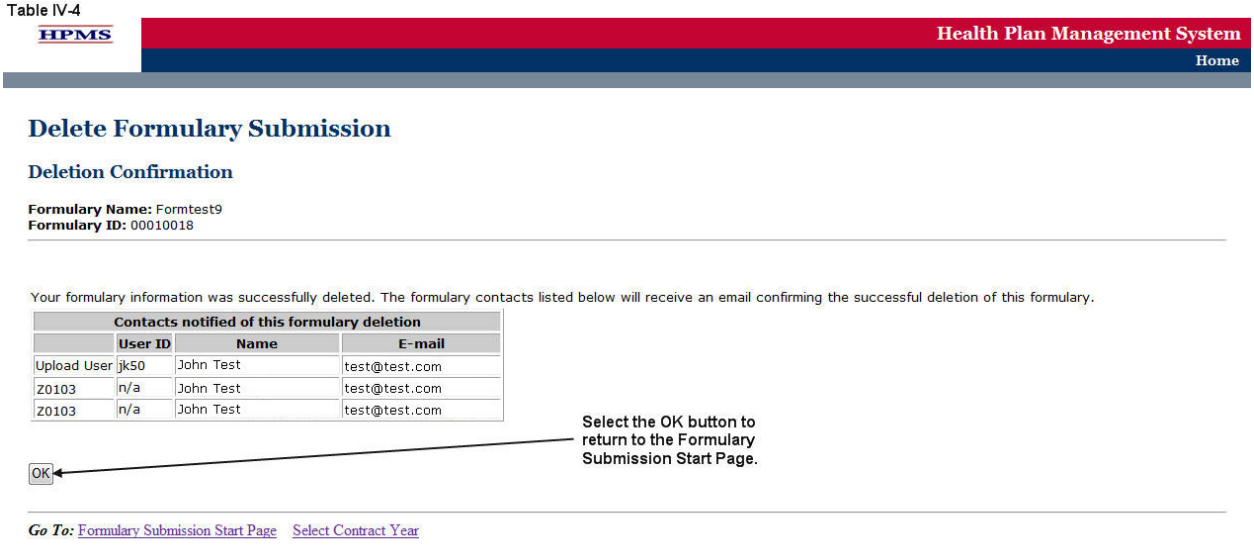
Table IV-3



STEP 5

On the **Delete a Formulary Submission - Deletion Confirmation** page (Table IV-4), select the OK button to return to the Formulary Submission Start Page.

Table IV-4



V. FORMULARY FILE REPORTS

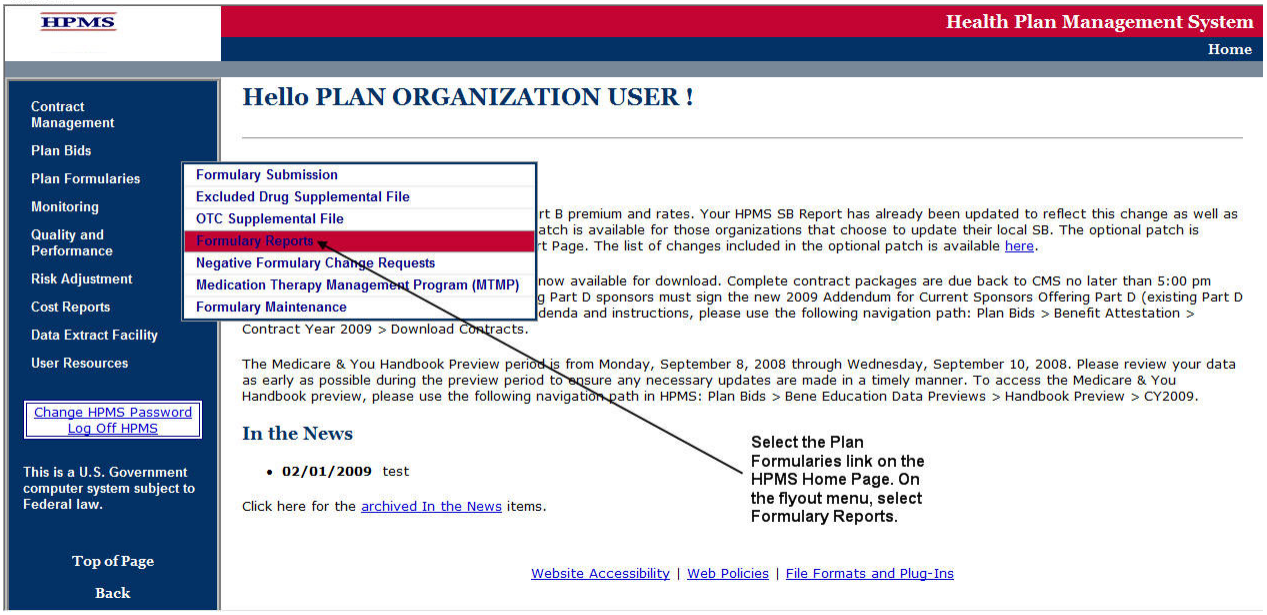
The **Formulary Reports** functionality provides access to a variety of formulary-related information to assist in the formulary submission process. This section provides detailed information on the following reports:

- Formulary/Bid Contact Report,
- Formulary Change Notification Report,
- Formulary Status History Report,
- Formulary Therapeutic Class and Category Change Notification Report, and
- Formulary Crosswalk Report.

STEP 1

As shown in Table V-1, on the **HPMS Home Page** select the **Plan Formularies** link in the left-hand navigation bar. On the flyout menu select the **Formulary Reports** link. This will take you to the Formulary Reports Contract Year Selection page.

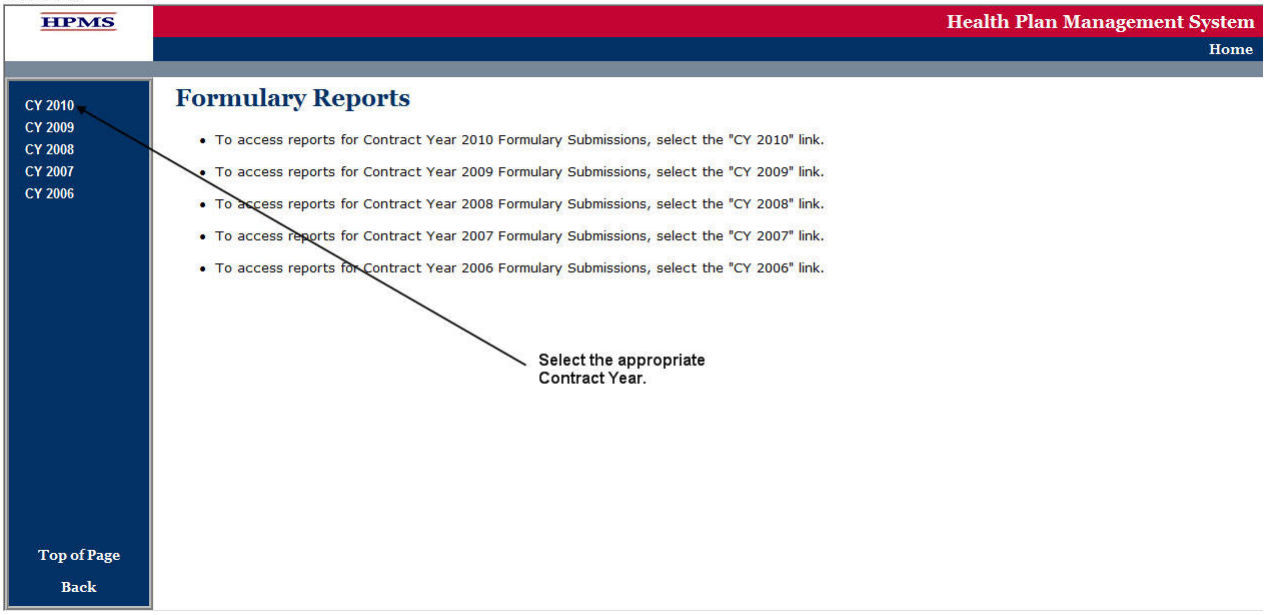
Table V-1



STEP 2

On the **Formulary Reports Contract Year Selection** page (Table V-2) select the appropriate Contract Yearlink. This will take you to the Formulary Reports – Select a Report page.

Table V-2



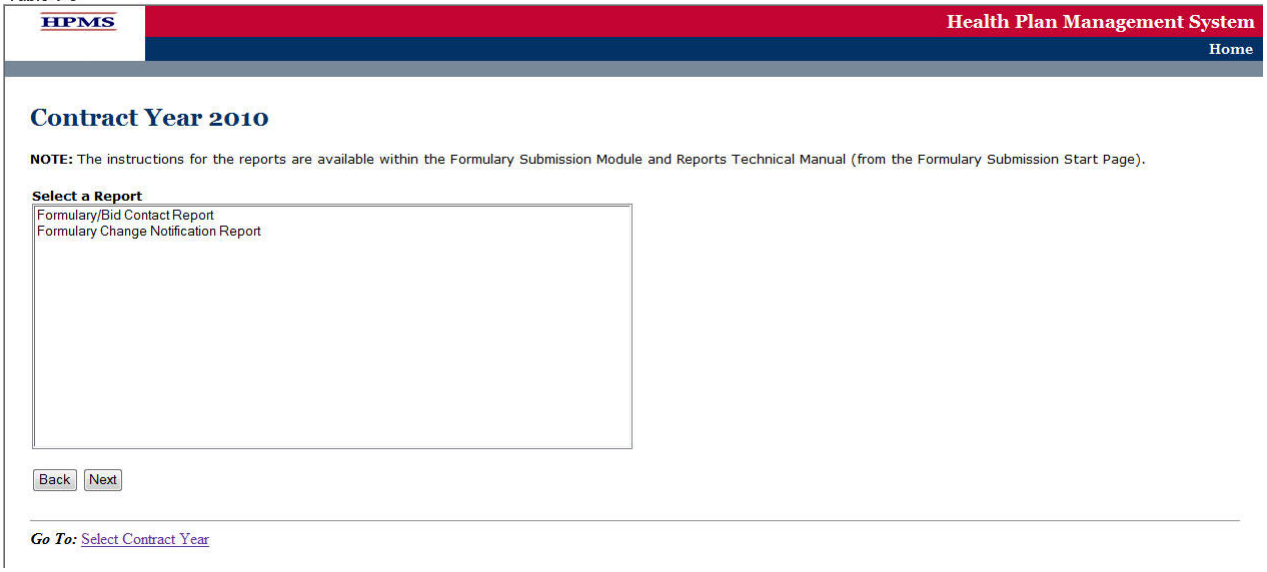
FORMULARY/BID CONTACT REPORT

The **Formulary/Bid Contact Report** provides contact information at the "Contract Level" and "Plan Level" for one or more contract(s).

STEP 1

On the **Formulary Reports – Select a Report** page (Table V-3) select Formulary/Bid Contact Report. This will take you to the Formulary Bid Report Contract Selection page.

Table V-3



STEP 2

On the **Formulary Bid Report Contract Selection** page (Table V-4) select the desired Contract Number(s) and click on the Next button. This will take you to the Formulary/Bid Contact Report (Table V-5).

IMPORTANT NOTE: If the information from the Formulary/Bid Contact Report is incorrect, please update the "Contact Information" in the HPMS Contract Management Module.

Table V-4

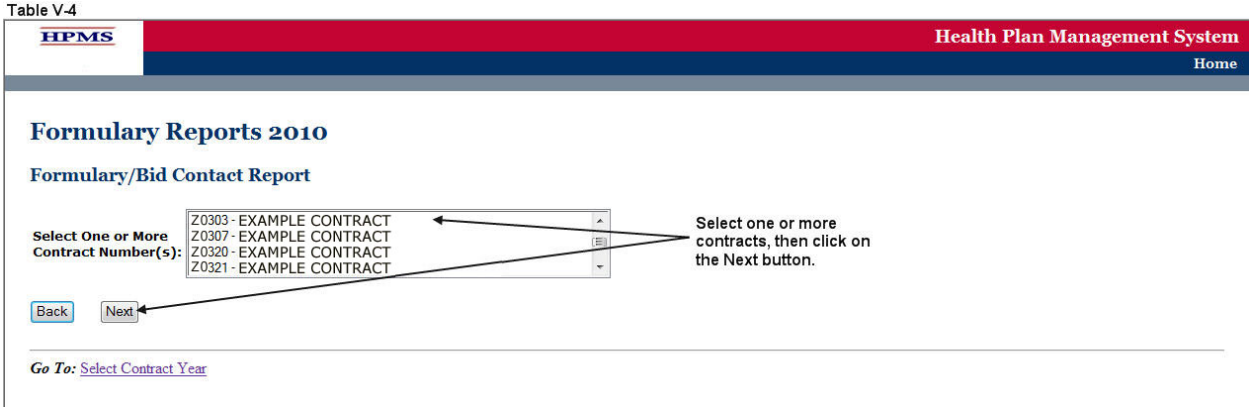
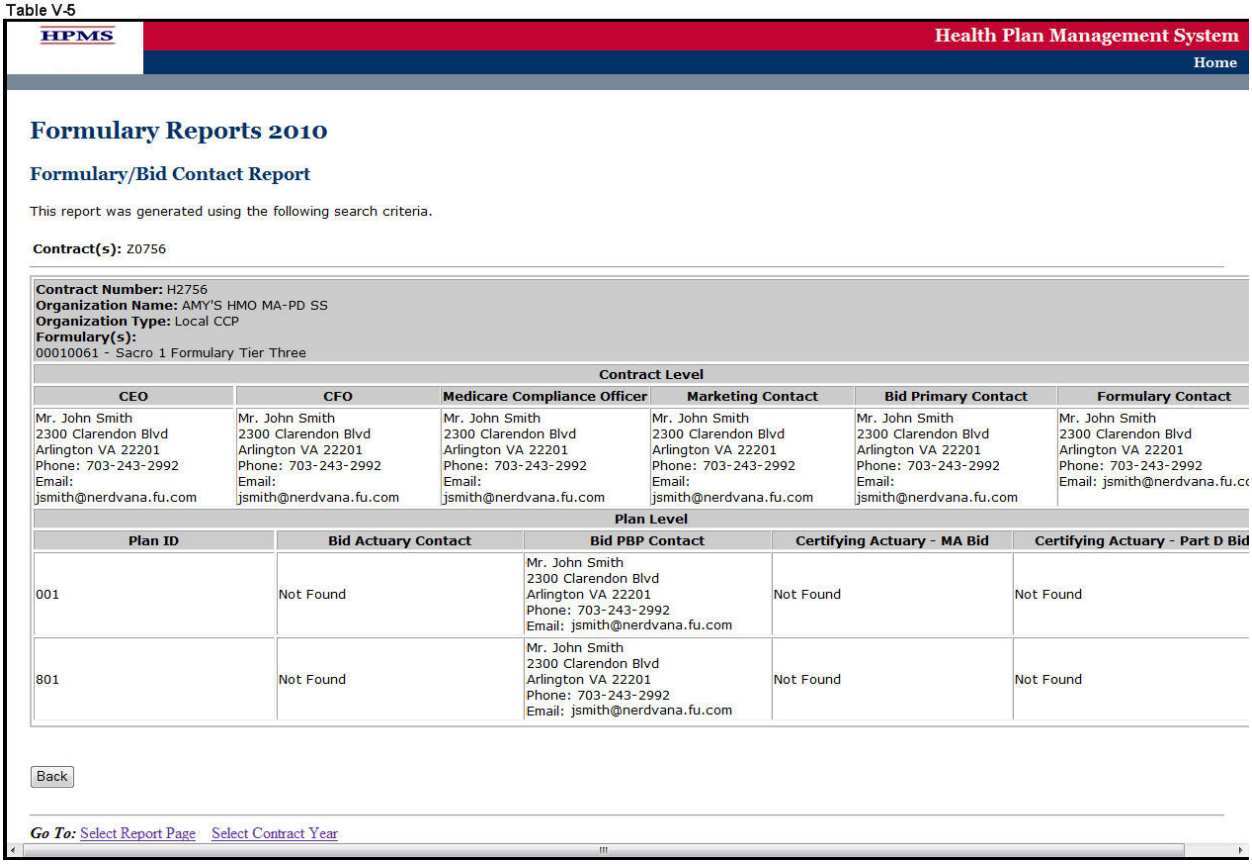


Table V-5



FORMULARY CHANGE NOTIFICATION REPORT

The **Formulary Change Notification Report** provides a comparison of data between two submitted formularies. You can compare the content of two submissions from one formulary or differences between two different formularies.

STEP 1

On the **Formulary Reports – Select a Report** page (Table V-3) select **Formulary Change Notification Report**. This will take you to the Formulary Change Notification Report selection criteria page.

STEP 2

On the **Formulary Change Notification Report selection criteria** page (Table V-6) select the desired Base Formulary ID and Version, as well as the Comparison Formulary ID and Version. (Version(s) will appear for selection after you select the Formulary ID and Comparison Formulary ID.) Then click on the Next button. This will take you to the **Formulary Change Notification Report** (Table V-7).

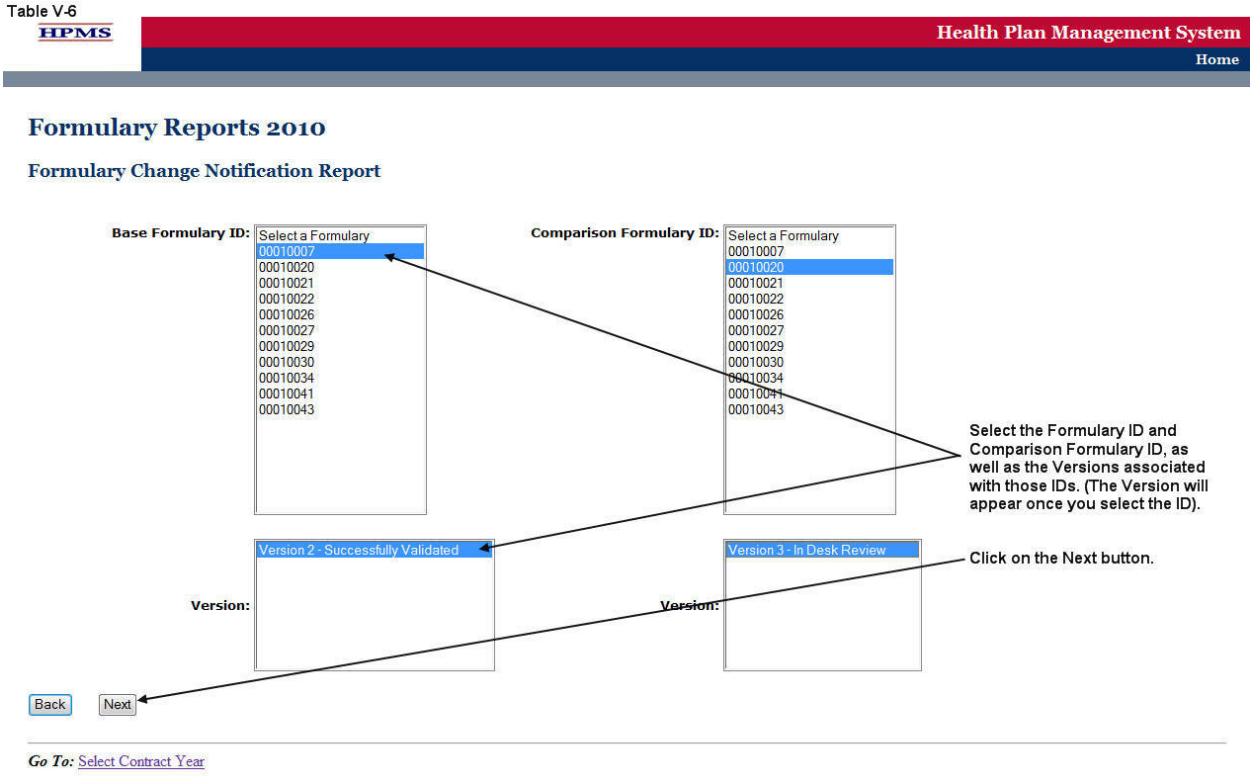
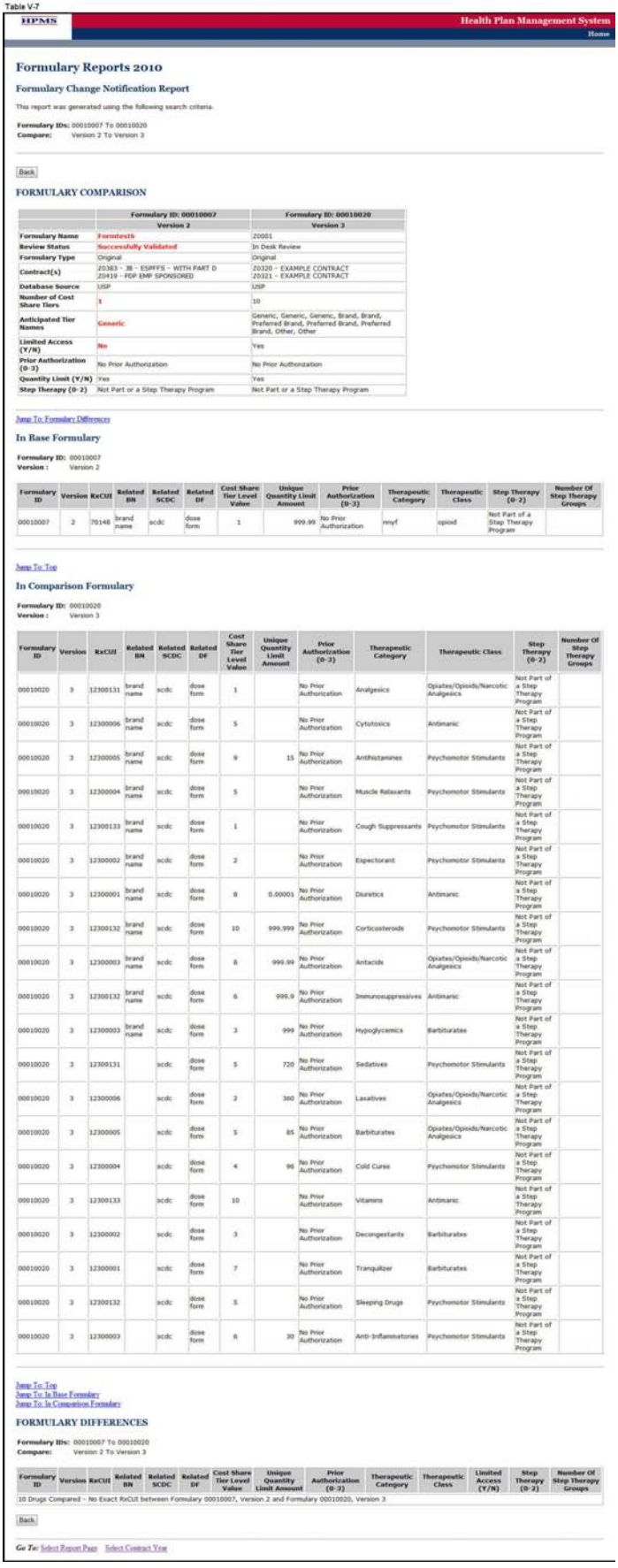


Table V-7



HPMS — Health Plan Management System — Home

Formulary Reports 2010

Formulary Change Notification Report

This report was generated using the following search criteria.

Formulary IDs: 00010007 To 00010020
Compare: Version 2 To Version 3

Back

FORMULARY COMPARISON

	Formulary ID: 00010007 Version 2	Formulary ID: 00010020 Version 3
Formulary Name	Formtest6	Z0001
Review Status	Successfully Validated	In Desk Review
Formulary Type	Original	Original
Contract(s)	Z0383 - JB - ESPFFS - WITH PART D Z0419 - PDP EMP SPONSORED	Z0320 - EXAMPLE CONTRACT Z0321 - EXAMPLE CONTRACT
Database Source	USP	USP
Number of Cost Share Tiers	1	10
Anticipated Tier Names	Generic	Generic, Generic, Generic, Brand, Brand, Preferred Brand, Preferred Brand, Preferred Brand, Other, Other
Limited Access (Y/N)	No	Yes
Prior Authorization (0-3)	No Prior Authorization	No Prior Authorization
Quantity Limit (Y/N)	Yes	Yes
Step Therapy (0-2)	Not Part or a Step Therapy Program	Not Part or a Step Therapy Program

Jump To: Formulary Differences

In Base Formulary

Formulary ID: 00010007
Version : Version 2

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Amount	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Step Therapy (0-2)	Number Of Step Therapy Groups
00010007	2	70148	brand name	scdc	dose form	1	999.99	No Prior Authorization	rnyf	opiod	Not Part of a Step Therapy Program	

Jump To: Top

In Comparison Formulary

Formulary ID: 00010020
Version : Version 3

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Amount	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Step Therapy (0-2)	Number Of Step Therapy Groups
00010020	3	12300133	brand name	scdc	dose form	1		No Prior Authorization	Analgesics	Opiates/Opioids/Narcotic Analgesics	Not Part of a Step Therapy Program	
00010020	3	12300006	brand name	scdc	dose form	5		No Prior Authorization	Cytotoxics	Antimanic	Not Part of a Step Therapy Program	
00010020	3	12300005	brand name	scdc	dose form	9	15	No Prior Authorization	Antihistamines	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300004	brand name	scdc	dose form	5		No Prior Authorization	Muscle Relaxants	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300133	brand name	scdc	dose form	1		No Prior Authorization	Cough Suppressants	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300002	brand name	scdc	dose form	2		No Prior Authorization	Expectorant	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300001	brand name	scdc	dose form	8	0.0001	No Prior Authorization	Diuretics	Antimanic	Not Part of a Step Therapy Program	
00010020	3	12300132	brand name	scdc	dose form	10	999.999	No Prior Authorization	Corticosteroids	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300003	brand name	scdc	dose form	8	999.99	No Prior Authorization	Antacids	Opiates/Opioids/Narcotic Analgesics	Not Part of a Step Therapy Program	
00010020	3	12300132	brand name	scdc	dose form	6	999.9	No Prior Authorization	Immunosuppressives	Antimanic	Not Part of a Step Therapy Program	
00010020	3	12300003	brand name	scdc	dose form	3	999	No Prior Authorization	Hypoglycemics	Barbiturates	Not Part of a Step Therapy Program	
00010020	3	12300131		scdc	dose form	5	720	No Prior Authorization	Sedatives	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300006		scdc	dose form	2	360	No Prior Authorization	Laxatives	Opiates/Opioids/Narcotic Analgesics	Not Part of a Step Therapy Program	
00010020	3	12300005		scdc	dose form	5	85	No Prior Authorization	Barbiturates	Opiates/Opioids/Narcotic Analgesics	Not Part of a Step Therapy Program	
00010020	3	12300004		scdc	dose form	4	96	No Prior Authorization	Cold Cures	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300133		scdc	dose form	10		No Prior Authorization	Vitamins	Antimanic	Not Part of a Step Therapy Program	
00010020	3	12300002		scdc	dose form	3		No Prior Authorization	Decongestants	Barbiturates	Not Part of a Step Therapy Program	
00010020	3	12300001		scdc	dose form	7		No Prior Authorization	Tranquilizer	Barbiturates	Not Part of a Step Therapy Program	
00010020	3	12300132		scdc	dose form	5		No Prior Authorization	Sleeping Drugs	Psychomotor Stimulants	Not Part of a Step Therapy Program	
00010020	3	12300003		scdc	dose form	6	30	No Prior Authorization	Anti-Inflammatories	Psychomotor Stimulants	Not Part of a Step Therapy Program	

Jump To: Top
Jump To: In Base Formulary
Jump To: In Comparison Formulary

FORMULARY DIFFERENCES

Formulary IDs: 00010007 To 00010020
Compare: Version 2 To Version 3

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Amount	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Limited Access (Y/N)	Step Therapy (0-2)	Number Of Step Therapy Groups
10 Drugs Compared - No Exact RxCUI between Formulary 00010007, Version 2 and Formulary 00010020, Version 3													

Back

Go To: Select Report Page Select Contract Year

FORMULARY STATUS HISTORY REPORT

The **Formulary Status History Report** provides detailed status information on all versions for a given formulary ID.

Detailed information relating to this Report will be released at a later date.

FORMULARY THERAPEUTIC CLASS AND CATEGORY CHANGE NOTIFICATION REPORT

The **Formulary Therapeutic Class and Category Change Notification Report** provides a comparison of data between two submitted formularies versions and displays differences in the Therapeutic Class and Category. You can compare the content of two submissions from one formulary or differences between two different formularies.

Detailed information relating to this Report will be released at a later date.

FORMULARY CROSSWALK REPORT

The **Formulary Crosswalk Report** displays information about which formularies are associated to a selected contract's plans.

Detailed information relating to this Report will be released at a later date.

VI. How To Submit Supplemental Files

As part of the formulary submission process, you will be required to submit certain supplemental files depending on what is included in your bid. This section provides detailed information on the how to submit the following supplemental files:

- Gap Coverage,
- Free First Fill,
- Home Infusion Drug,
- Over-the-Counter, and
- Excluded Drugs.

On June 8, 2009, the Formulary Supplemental Submissions and Reports functionality will be released to support the submission of gap coverage, free first fill, home infusion drug, over-the-counter, and excluded drug supplemental files. Organizations must submit this supplemental information for each plan offering this coverage. The supplemental files cannot be loaded until the organization has successfully submitted their related bid(s).

Detailed information relating to this Chapter will be released when the CY 2010 Formulary Supplemental Submissions and Reports functionality is released.

VII. SUPPLEMENTAL FILE REPORTS

The **Formulary Supplemental File Reports** provide access to a variety of formulary-related information to assist you in the formulary supplemental submission process. This section provides detailed information on the following reports:

- Gap Coverage Status History Report,
- Free First Fill Status History Report, and,
- Home Infusion Status History Report.

On June 8, 2009, the Formulary Supplemental Submissions and Reports functionality will be released to support the submission of gap coverage, free first fill, home infusion drug, over-the-counter, and excluded drug supplemental files. Organizations must submit this supplemental information for each plan offering this coverage. The supplemental files cannot be loaded until the organization has successfully submitted their related bid(s).

Detailed information relating to this Chapter will be released when the CY 2010 Formulary Supplemental Submissions and Reports functionality is released.

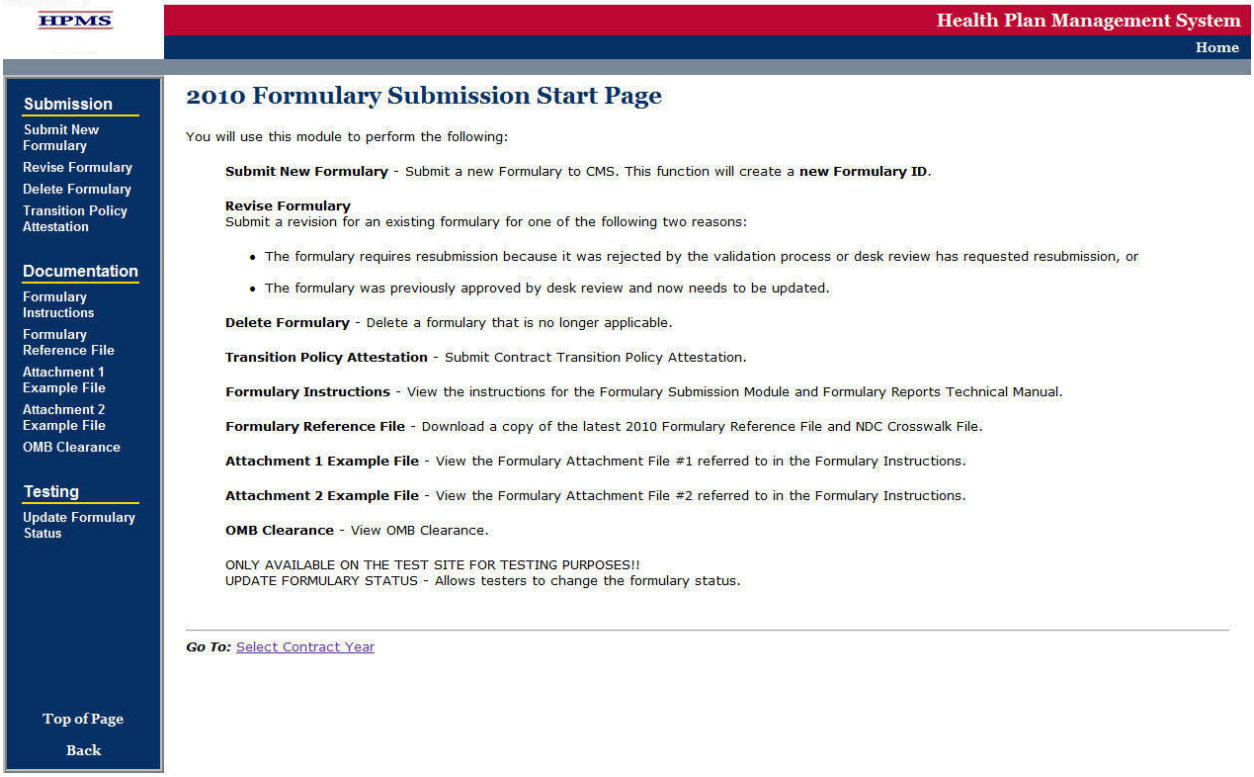
VIII. How To Submit The Transition Policy Attestation

All organizations must attest to their formulary Transition Policy. While the formulary submission is not dependent on whether you have completed the Transition Policy attestation in HPMS, you must successfully complete the Transition Policy attestation (i.e., respond "Yes" to all questions) before CMS will renew or approve your Part D contract.

Step 1

As shown in Table VIII-1, on the **HPMS Home Page** select the **Transition Policy Attestation** link in the left-hand navigation bar. This will take you to the Attestation Submission Contract Selection page.

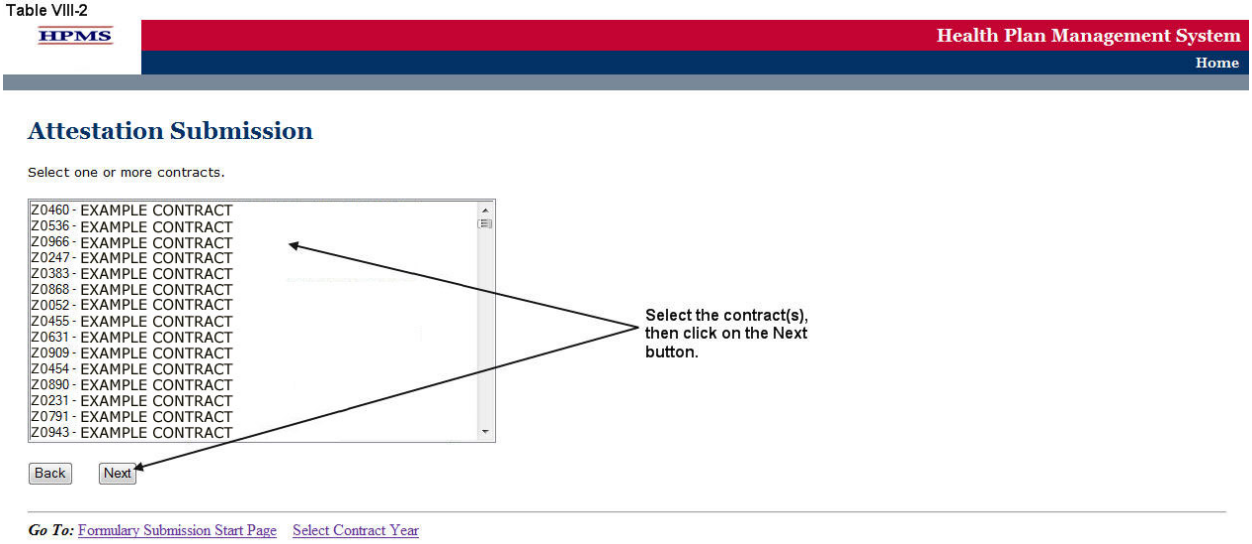
Table VIII-1



Step 2

On the **Attestation Submission Contract Selection** page (Table VIII-2), select the contract(s) for which you are submitting your attestation. Then click on the Next button. This will take you to the Attestation Submission – Attestation Questions page.

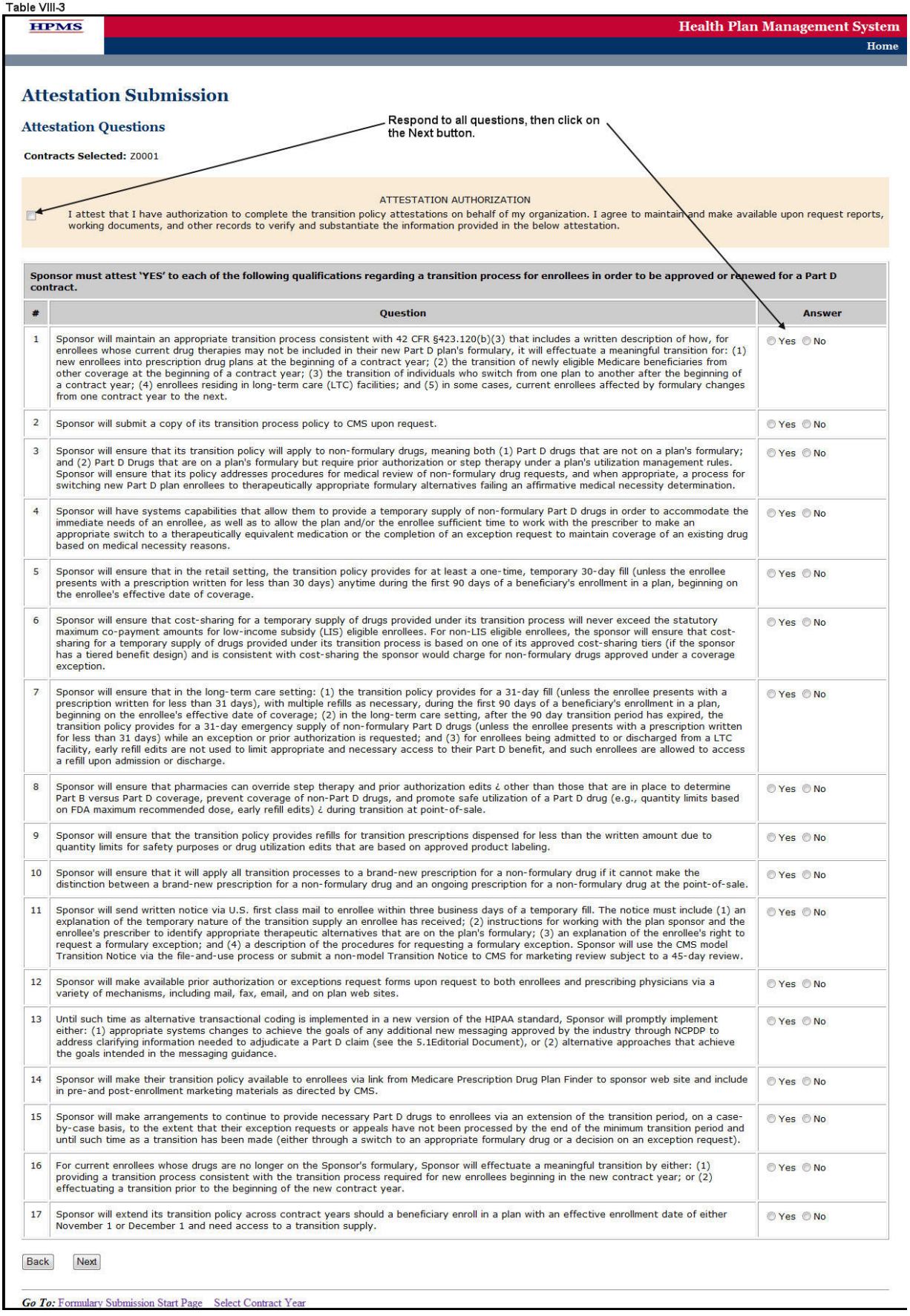
Table VIII-2



STEP 3

On the **Attestation Submission – Attestation Questions** page (Table VIII-3), first indicate that you are authorized to submit the Attestation on behalf of your organization. Then respond "Yes" or "No" to each question provided. Once you have finished responding to all questions, click on the Next button. This will take you to the Attestation Submission – Verify Attestation page.

Table VIII-3


HPMS
Health Plan Management System
Home
Attestation Submission
Attestation Questions
Respond to all questions, then click on the Next button.
Contracts Selected: Z0001
ATTESTATION AUTHORIZATION
I attest that I have authorization to complete the transition policy attestations on behalf of my organization. I agree to maintain and make available upon request reports, working documents, and other records to verify and substantiate the information provided in the below attestation.
Sponsor must attest 'YES' to each of the following qualifications regarding a transition process for enrollees in order to be approved or renewed for a Part D contract.
| Question | Answer
1 | Sponsor will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans at the beginning of a contract year; (2) the transition of newly eligible Medicare beneficiaries from other coverage at the beginning of a contract year; (3) the transition of individuals who switch from one plan to another after the beginning of a contract year; (4) enrollees residing in long-term care (LTC) facilities; and (5) in some cases, current enrollees affected by formulary changes from one contract year to the next. | Yes No
2 | Sponsor will submit a copy of its transition process policy to CMS upon request. | Yes No
3 | Sponsor will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on a plan's formulary; and (2) Part D Drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules. Sponsor will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. | Yes No
4 | Sponsor will have systems capabilities that allow them to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons. | Yes No
5 | Sponsor will ensure that in the retail setting, the transition policy provides for at least a one-time, temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage. | Yes No
6 | Sponsor will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS eligible enrollees, the sponsor will ensure that cost-sharing for a temporary supply of drugs provided under its transition process is based on one of its approved cost-sharing tiers (if the sponsor has a tiered benefit design) and is consistent with cost-sharing the sponsor would charge for non-formulary drugs approved under a coverage exception. | Yes No
7 | Sponsor will ensure that in the long-term care setting: (1) the transition policy provides for a 31-day fill (unless the enrollee presents with a prescription written for less than 31 days), with multiple refills as necessary, during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage; (2) in the long-term care setting, after the 90 day transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested; and (3) for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge. | Yes No
8 | Sponsor will ensure that pharmacies can override step therapy and prior authorization edits ¿ other than those that are in place to determine Part B versus Part D coverage, prevent coverage of non-Part D drugs, and promote safe utilization of a Part D drug (e.g., quantity limits based on FDA maximum recommended dose, early refill edits) ¿ during transition at point-of-sale. | Yes No
9 | Sponsor will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling. | Yes No
10 | Sponsor will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale. | Yes No
11 | Sponsor will send written notice via U.S. first class mail to enrollee within three business days of a temporary fill. The notice must include (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the plan sponsor and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary; (3) an explanation of the enrollee's right to request a formulary exception; and (4) a description of the procedures for requesting a formulary exception. Sponsor will use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a 45-day review. | Yes No
12 | Sponsor will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on plan web sites. | Yes No
13 | Until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, Sponsor will promptly implement either: (1) appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim (see the 5.1Editorial Document), or (2) alternative approaches that achieve the goals intended in the messaging guidance. | Yes No
14 | Sponsor will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to sponsor web site and include in pre-and post-enrollment marketing materials as directed by CMS. | Yes No
15 | Sponsor will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request). | Yes No
16 | For current enrollees whose drugs are no longer on the Sponsor's formulary, Sponsor will effectuate a meaningful transition by either: (1) providing a transition process consistent with the transition process required for new enrollees beginning in the new contract year; or (2) effectuating a transition prior to the beginning of the new contract year. | Yes No
17 | Sponsor will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. | Yes No
Back
Next
Go To: Formulary Submission Start Page Select Contract Year

STEP 4

On the **Attestation Submission – Verify Attestation** page (Table VIII-4), verify the responses you provided then click on the Next button to submit your attestation. This will take you to the Attestation Submission –Submission Confirmation page (Table VIII-5).

Table VIII-4

HPMS — Health Plan Management System

Home

Attestation Submission

Verify Attestation

Please note that your data has not yet been submitted.

Contracts Selected: Z0001

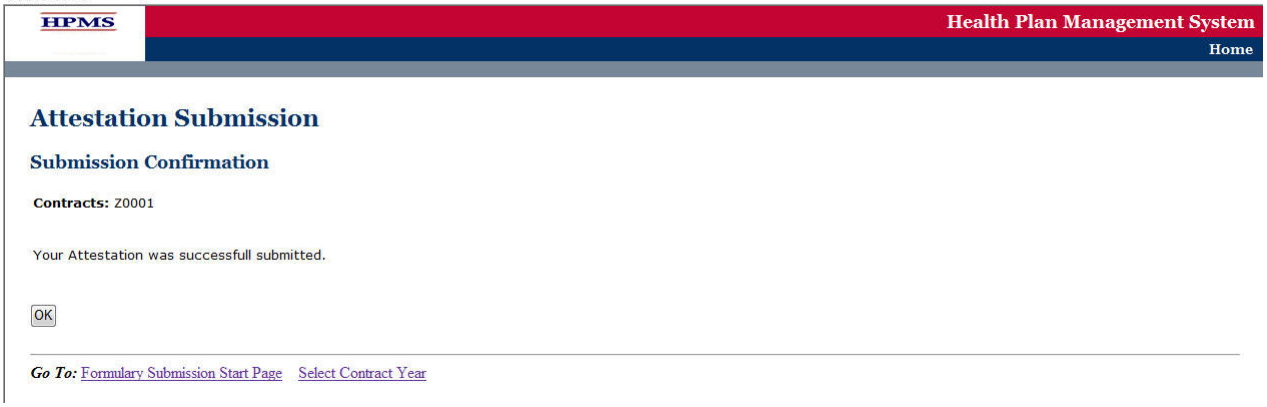
Sponsor must attest 'YES' to each of the following qualifications regarding a transition process for enrollees in order to be approved or renewed for a Part D contract.

#	Question	Answer
1	Sponsor will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans at the beginning of a contract year; (2) the transition of newly eligible Medicare beneficiaries from other coverage at the beginning of a contract year; (3) the transition of individuals who switch from one plan to another after the beginning of a contract year; (4) enrollees residing in long-term care (LTC) facilities; and (5) in some cases, current enrollees affected by formulary changes from one contract year to the next.	Yes
2	Sponsor will submit a copy of its transition process policy to CMS upon request.	Yes
3	Sponsor will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on a plan's formulary; and (2) Part D Drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules. Sponsor will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.	Yes
4	Sponsor will have systems capabilities that allow them to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.	Yes
5	Sponsor will ensure that in the retail setting, the transition policy provides for at least a one-time, temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.	Yes
6	Sponsor will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS eligible enrollees, the sponsor will ensure that cost-sharing for a temporary supply of drugs provided under its transition process is based on one of its approved cost-sharing tiers (if the sponsor has a tiered benefit design) and is consistent with cost-sharing the sponsor would charge for non-formulary drugs approved under a coverage exception.	Yes
7	Sponsor will ensure that in the long-term care setting: (1) the transition policy provides for a 31-day fill (unless the enrollee presents with a prescription written for less than 31 days), with multiple refills as necessary, during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage; (2) in the long-term care setting, after the 90 day transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested; and (3) for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.	Yes
8	Sponsor will ensure that pharmacies can override step therapy and prior authorization edits ¿ other than those that are in place to determine Part B versus Part D coverage, prevent coverage of non-Part D drugs, and promote safe utilization of a Part D drug (e.g., quantity limits based on FDA maximum recommended dose, early refill edits) ¿ during transition at point-of-sale.	Yes
9	Sponsor will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling.	Yes
10	Sponsor will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.	Yes
11	Sponsor will send written notice via U.S. first class mail to enrollee within three business days of a temporary fill. The notice must include (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the plan sponsor and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary; (3) an explanation of the enrollee's right to request a formulary exception; and (4) a description of the procedures for requesting a formulary exception. Sponsor will use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a 45-day review.	Yes
12	Sponsor will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on plan web sites.	Yes
13	Until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, Sponsor will promptly implement either: (1) appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim (see the 5.1Editorial Document), or (2) alternative approaches that achieve the goals intended in the messaging guidance.	Yes
14	Sponsor will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to sponsor web site and include in pre- and post-enrollment marketing materials as directed by CMS.	Yes
15	Sponsor will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).	Yes
16	For current enrollees whose drugs are no longer on the Sponsor's formulary, Sponsor will effectuate a meaningful transition by either: (1) providing a transition process consistent with the transition process required for new enrollees beginning in the new contract year; or (2) effectuating a transition prior to the beginning of the new contract year.	Yes
17	Sponsor will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.	Yes

Back | Submit ← Click on the Submit button to submit your attestation.

Go To: Formulary Submission Start Page Select Contract Year

Table VIII-5


HPMS
Health Plan Management System
Home
Attestation Submission
Submission Confirmation
Contracts: Z0001
Your Attestation was successfull submitted.
OK
Go To: Formulary Submission Start Page
Select Contract Year

APPENDIX A: CY 2010 FORMULARY FILE RECORD LAYOUT

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".TXT"

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
RXCUI	NUMBER Always Required	Max. of 8 digits	RxNorm concept unique identifier from the active Formulary Reference File.	210597
Tier_Level	CHAR Always Required	2	Defines the Cost Share Tier Level Associated with the drug. Assumption is that the drug is assigned to only one tier value. These values are consistent with the selection of tier level options available to data entry users in the Plan Benefit Package software.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6 7 = Tier Level 7 8 = Tier Level 8 9 = Tier Level 9 10 = Tier Level 10
Drug_Type_Label	CHAR Always Required	1	Defines the Drug Type Label for the drug. Enter the label value for the Drug Type from the defined list of labels.	1 = Generic 2 = Preferred Generic 3 = Non-Preferred Generic 4 = Brand 5 = Preferred Brand 6 = Non-Preferred Brand
Quantity_Limit_YN	CHAR Always Required	1	Does the drug have a quantity limit restriction?	0 = No Quantity Limits 1 = Quantity Limits Apply
Quantity_Limit_Amount	NUM Sometimes Required	7	If Quantity_Limit_YN = 1 (Limits Apply), enter the quantity limit unit amount for a given prescription or time period. The units for this amount must be defined by a unit of measure e.g. number of tablets, milliliters, grams, etc. If the Quantity_Limit_YN = 0 (No Limits), leave this field blank. The maximum number of decimal points that will be accepted is 5, i.e., "9.99999."	9

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
			The maximum number that will be accepted is "9999.99."	
Quantity_Limit_Days	NUM Sometimes Required	3	Enter the number of days associated with the quantity limit. If the Quantity_Limit_YN field is 0 (No), then leave this field blank. The maximum logical number that will be accepted is "999".	60 (e.g. 9 tablets every 60 days)
Prior_Authorization_Type	CHAR Always Required	1	Is prior authorization required for the drug?	0 = No Prior Authorization 1 = Prior Authorization Applies 2 = Prior Authorization Applies to New Starts Only 3 = Part B vs. Part D Prior Authorization Only
Prior_Authorization_Group_ Desc	CHAR Sometimes Required	100	Description of the drug's prior authorization group as it will appear on the submitted prior authorization attachment. The group name may represent a drug category or class or may simply be the name of the drug if no other grouping structure applies. If response to Prior_Authorization_Type is 0 (No) or 3 (Part B vs. Part D Authorization Only), then leave this field blank.	Antiemetics
Limited_Access_YN	CHAR Always Required	1	Is access to this drug limited to certain pharmacies?	1 = Yes 0 = No
Therapeutic_Category_Name	CHAR Always Required	100	Enter the name of the category for the drug.	Analgesics
Therapeutic_Class_Name	CHAR Always Required	100	Enter the name of the class for the drug.	Opioid Analgesics
Step_Therapy_Type	CHAR Always Required	1	Does step therapy apply to this drug? Note: Prerequisite (Step 1) drugs should also have a value of 1 in this field.	0 = Not Part of a Step Therapy Program 1 = Step Therapy Applies 2 = Step Therapy Applies to New Starts

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
				Only
Step_Therapy_Total_Groups	NUM Sometimes Required	2	Enter the total number of step therapy drug treatment groups in which the drug is included. If response to Step_Therapy_Type = 0 (No), then leave this field blank. The maximum logical number that will be accepted is "99."	3
The remaining two fields described below should be repeated as a group or unit in the file. For example, for a given drug used in multiple Step Therapy programs, the values for Step_Therapy_Group_Desc = "CHF Therapy" and Step_Therapy_Step_Value = 4 should be included in adjacent columns in the file. Likewise, the values for Step_Therapy_Group_Desc = "Angina Therapy" and Step_Therapy_Step_Value = 1 should be included in additional adjacent columns in the file. Likewise, the values for Step_Therapy_Group_Desc = "CVD Therapy" and Step_Therapy_Step_Value = 5 should be included in additional adjacent columns in the file.				
Step_Therapy_Group_Desc	CHAR Sometimes Required	100	Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Total_Groups. If response to Step_Therapy_Type = 0 (No), then leave this field blank. Note: For a given RXCUI, each Group Description must be unique.	Step_Therapy_Group_Desc = "CHF Therapy" Step_Therapy_Group_Desc = "Angina Therapy" Step_Therapy_Group_Desc = "CVD Therapy"
Step_Therapy_Step_Value	NUM Sometimes Required	2	Identifies the step number or level within the sequence for the Step Therapy Group. Field should be repeated in the record based upon the number of groups declared in Step_Therapy_Total_Groups AND in the same order as Step_Therapy_Group_Desc If response to Step_Therapy_Type = 0 (No), then leave this field blank. The range of valid accepted values is 1 to 99.	Step_Therapy_Step_Value = 4 (e.g. Step 4 of 6) Step_Therapy_Step_Value = 1 (e.g. Step 1 of 3) Step_Therapy_Step_Value = 5 (e.g. Step 5 of 5)

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

APPENDIX B: UPLOAD FILE FORMATS

FORMULARY FILE INSTRUCTIONS

The formulary file must be created in an ASCII File Tab delimited format and contain one proxy RXCUI record for each drug offered with an organization's benefit plan(s). The Appendix A: Formulary File Record Layout is provided for your reference. Please note that only proxy RXCUI s provided in the CY 2010 Formulary Reference File maybe uploaded. All other codes will be rejected by the HPMS Formulary Validation Process.

The following is a "field by field" description of how to structure your formulary file for upload into HPMS. Please note that every field is labeled either "Required," "Optional," or "Conditional." The conditional fields should be populated if the condition is met as outlined below. When an optional and/or conditional field is left blank, the blank must be represented by a tab delimiter.

NOTE: Attachment 1 (and 2) Example Files (located on the Formulary Submission Start Page) provides sample records for a formulary.

The upload validation edits are explained in further detail within each field description. A formulary will be rejected if the validation edits are not met.

Field 1 – RXCUI:
REQUIRED: Each record should include an up to 8-digit numeric RXCUI associated with the formulary. The list of acceptable RXCUIs can be found in the CY 2010 Formulary Reference RXCUI File. RXCUIs should only be entered once in this formulary file.

Field 2 – Tier_Level:
REQUIRED: Enter the cost share tier level value associated with the drug. Include a value from 1 to 10 only. A number outside of this range will result in an upload error. If cost share tiering does not apply, include the value "1" in this field.

> **NOTE:** The maximum value entered for this field may NOT be greater than the value entered for the number of cost share tiers in the HPMS Formulary Submission Data Entry Web Interface. If these values are inconsistent an upload error will result.

Field 3 – Drug_Type_Label:
REQUIRED: Enter a drug type label value associated with the drug. Include a value of 1 to 6 only. A number outside of this range will result in an upload error.

Field 4 – Quantity_Limit_YN:
REQUIRED: This field should be set to a value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the drug has a restriction on the quantity that is available; otherwise set the value to 0 if there are no restrictions. Examples of quantity limits include the following:

- Simvastatin 40mg tablets - 30 tablets/30 days
- Latanoprost 0.005% drops – 2.5 ml/30 days
- Albuterol HFA MDI – 8.5 grams/30days

Field 5 - Quantity_Limit_Amount:
CONDITIONAL: If the **Quantity_Limit_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_YN** field is 1, include the quantity limit unit amount. The unit amount for this field refers to unit values such as the number of tablets or the number of grams for the drug. For example, for a quantity limit that includes 9 tablets every 60 days, this field should indicate a value of 9.

Field 6 - Quantity_Limit_Days:
CONDITIONAL: If the **Quantity_Limit_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_YN** field is 1, include the quantity limit day amount for this drug. For example, for a quantity limit that includes 9 tablets every 60 days, this field should indicate a value of 60.

Field 7 – Prior_Authorization_Type:
REQUIRED: This value should be set to value of 0 through 3, where 0 = No Prior Authorization, 1 = Prior Authorization Applies, 2 = Prior Authorization Applies to New Starts Only, and 3 = Part B vs. Part D Prior Authorization Only. NOTE: If the user selected **Yes** to the Prior Authorization question in the HPMS Data Entry Web Interface, then one or more RXCUI records must have a value of 1 or greater for this field. If these values are inconsistent, an upload error will result.

Please note that the intent of the PA Type 2 is for identification of applicable six class drugs that require PA during the initial formulary review and approval process. These values should not change after initial formulary approval.

Field 8 – Prior_Authorization_Group_Desc:
CONDITIONAL: If Prior Authorization Type is 0 or 3, then leave this field blank. If Prior Authorization Type is 1 or 2, then include the description of the drug's prior authorization group as it will appear on the Prior Authorization Attachment. The group name may represent a drug category or class or may be the name of the drug if no other grouping structure applies. RXCUIS should only be grouped together if the prior authorization criteria are the same for all RXCUIs within that group description.

Field 9 – Limited_Access_YN:
REQUIRED: The value should be set to 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if access to the drug is limited to certain pharmacies; otherwise set the value to 0 to indicate that the drug is not restricted to certain pharmacies.

NOTE: If the user selected "Yes" to the limited access question in the HPMS data entry web interface, then one or more RXCUI records must have a value of 1 for this field. If these values are inconsistent an upload error will result.

Field 10 – Therapeutic_Category_Name:

REQUIRED: Enter the name of the category for this drug.

Field 11 – **Therapeutic_Class_Name**:
REQUIRED: Enter the name of the class for this drug.

NOTE: If the classification system you have chosen, such as the USP Model Guidelines, provides a category name but no class name, the category name should be repeated in this field.

Field 12 – **Step_Therapy_Type**:
REQUIRED: This value should be set to a value of 0, 1, or 2, where 0 = Not Part of a Step Therapy Program, 1 = Step Therapy Applies, and 2 = Step Therapy Applies to New Starts Only.

> **NOTE**: If the user selected **Yes** to the Step Therapy question in the HPMS Data Entry Web Interface, then one or more RXCUI records must have a value of 1 or greater for this field. If these values are inconsistent, an upload error will result.
>
> Please note that the intent of the ST Type 2 is for identification of applicable six class drugs that require ST during the initial formulary review and approval process. These values should not change after initial formulary approval.

Field 13 – **Step_Therapy_Total_Groups:**
CONDITIONAL: This field should include a value that indicates the number of step therapy drug treatment groups in which the drug is a member. The value included in this field may not exceed 2 digits in length. This field should contain a value if **Step_Therapy_Type** = 1 or greater. If step therapy does not apply to a given drug, then leave this field blank by providing a tab delimiter.

Field 14 – **Step_Therapy_Groups_Desc**:
CONDITIONAL: If the user selects **Yes** to having one or more drugs with step therapy management in the HPMS Data Entry Web Interface, then the user must provide a description of the step therapy drug treatment group. This field should be repeated in the drug record (in an additional column) based upon the number of groups declared in **Step_Therapy_Total_Groups**. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter.

Field 15 – **Step_Therapy_Step_Value**:
CONDITIONAL: If the user selects **Yes** to having one or more drugs with step therapy management in the HPMS Data Entry Web Interface, then the user must include a value in this field that represents the unique step number within the sequence of steps for the treatment group identified in Field 12. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter. Prerequisite (Step 1) drugs should be indicated by a value of 1. This field should be repeated in the record (in an additional column) based upon number of groups declared in **Step_Therapy_Total_Groups** AND in the same order as **Step_Therapy_Group_Desc**. For example, if an RXCUI has 3 step therapy treatment groups declared in the Step_Therapy_Total_Groups field, then three sets of values should be defined for Step_Therapy_Group_Desc and Step_Therapy_Step_Value as follows:

Step Therapy Treatment Group 1 Values –
Step_Therapy_Group_Desc = "CHF Therapy"
And
Step_Therapy_Step_Value = 4

Step Therapy Treatment Group 2 Values –
Step_Therapy_Group_Desc = "Angina Therapy"
And
Step_Therapy_Step_Value = 2

Step Therapy Treatment Group 3 Values –
Step_Therapy_Group_Desc = "CVD Therapy"
And
Step_Therapy_Step_Value = 5

PRIOR AUTHORIZATION FILE INSTRUCTIONS AND RECORD LAYOUT

If a formulary has prior authorization for one or more drugs, then the formulary upload submission must include an attachment that describes the specific prior authorization criteria. The criteria should be provided in a Tab Delimited Text File and field entries should be as succinct as possible. Provider questions, diagrams, and decision trees are not permitted. Further, if a drug has quantity limit restrictions, the applicable values must be entered on the formulary flat file, not the PA file. Consistent with the definition of a Part D drug, you must not list any uses for drugs within the document that are not FDA-approved or supported in the compendia. Please refer to the Field Descriptions below for details. References or citations are not required. When an optional field is left blank must be represented by a tab delimiter.

The **PA_Criteria_Change_Indicator** field has been added to the CY 2010 record layout. For a given PA Group Description, a "1" must be entered if the content of any CY 2010 PA elements have changed when compared to your approved CY 2009 PA criteria submission(s) as of March 24, 2009. In addition, if PA is required for drugs that are on your CY 2010 formulary that were either 1) not on the approved CY 2009 file, OR 2) did not previously require a PA for CY 2009, then a "1" must be entered. If the criteria are completely unchanged, a "0" must be entered.

Please Note: If the submitted formulary file contains only Prior Authorization Type 3 or Prior Authorization Type 3 and 0, the submitted Prior Authorization File should contain only one space; the user uploads a file that contains only one space.

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".TXT"

Field Name	Field Type	Field Length	Field Description
Prior_Authorization_	CHAR	100	Description of the prior authorization group as it

Field Name	Field Type	Field Length	Field Description
Group_Desc	Always Required		appears on the submitted formulary file. **This field must exactly match the value entered in the Prior_Authorization_Group_Desc field on the Formulary File.**
PA_Criteria_Change_ Indicator	CHAR Always Required	1	If the PA criteria content did not change for this group description compared to CY 2009, please place a "0" in this field. If this group description is new, or the criteria content changed in any way (e.g. additional restrictions), please place a "1" in this field".
Covered_Uses	CHAR Always Required	3000	Enter both the FDA-approved and off-label indications for which the drug(s) will be covered. At a minimum, you must enter the following in this field: "All FDA-approved indications not otherwise excluded from Part D." You may enter the statement "All medically accepted indications not otherwise excluded from Part D" if the PA will be approved for all non-excluded off-label uses in addition to the labeled indications. If only certain off-label uses will be approved by prior authorization, you should list the specific uses following the "All FDA-approved indications not otherwise excluded from Part D" statement.
Exclusion_Criteria	CHAR If applicable	2000	Describe any criteria (e.g. comorbid diseases, laboratory data, etc.) that would result in the exclusion of coverage for an enrollee.
Required_Medical_ Information	CHAR If applicable	2000	Enter laboratory, diagnostic, or other medical information required for initiation or continuation of the drug(s).
Age_Restrictions	CHAR If applicable	500	Enter age limitations or restrictions required for prior authorization approval.
Prescriber_Restrictions	CHAR If applicable	500	Description of prescriber attribute necessary for PA to be considered, e.g. specialist in a field or registered under a certain program.
Coverage_Duration	CHAR Always Required	100	Enter the duration for which the prior authorization will be approved.
Other_Criteria	CHAR If applicable	3000	Enter any other relevant criteria that cannot be otherwise classified into another existing field.

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

STEP THERAPY FILE INSTRUCTIONS

If a formulary has step therapy for one or more drugs, then the formulary upload submission must include an attachment that illustrates the detailed algorithms for all step therapy management programs in the formulary. The step therapy management algorithm file should be provided in ASCII Tab delimited text file format. .

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".TXT"

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Step_Therapy_Group_Desc	CHAR Always Required	100	Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Total_Groups in the Formulary File submission upload. Description of the step therapy group as it appears on the submitted formulary file. This field must exactly match the value entered in the Step_Therapy_Group_Desc field on the Formulary File. Note: For a given Rx CUI, each Group Description must be unique. Note: For each Step Therapy Group Description, there must be a Rx CUI with a Step Therapy Value equal to 1.	Step_Therapy_Group_Desc = "CHF Therapy" Step_Therapy_Group_Desc = "Angina Therapy" Step_Therapy_Group_Desc = "CVD Therapy"
Step_Therapy_Criteria	CHAR Always Required	4000	Description of the criteria of the step therapy drug.	

GAP COVERAGE, FREE FIRST FILL, AND HOME INFUSION RECORD LAYOUT

For each plan that offers Gap Coverage, Free First Fill, and/or Home Infusion Drug, the organization must submit a supplemental file that defines the covered drugs. The file must be created in an ASCII File format and contain one RXCUI record for each covered drug. The Supplemental File Record Layout is provided below for your reference. The supplemental file must only contain RXCUIs that exist in the associated formulary. If you include an RXCUI that is not part of the associated formulary, the file will be rejected by the HPMS Formulary Validation Process.

Note: If the plan offers gap coverage at the full tier level, you do not need to submit a supplemental file for the full tier

Required File Format = ASCII File
Do not include a header record
Filename extension should be ".TXT"

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RXCUI	NUMBER Always Required	Maximum of 8 digits	RXCUI concept unique identifier from the active Formulary Reference File.	210597

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

When submitting a monthly formulary update, you will be given the choice to use the last file submitted or upload a new file. We would expect that a new file upload would only be necessary if there are approved changes to the current formulary file that would also affect this file.

EXCLUDED DRUG RECORD LAYOUT

For each plan that offers Excluded Drugs as part of their supplemental coverage, the organization must submit a supplemental file that defines the covered drugs. The plan must choose their proxy NDC. The file must be created in an ASCII File format and contain one proxy NDC record for each covered drug defined by the variables provided in the Excluded Drug File Record Layout The Excluded Drug File Record Layout is provided below for your reference. The plan should submit one record for each covered brand (marketed under a NDA) and equivalent generic drug product (marketed under an ANDA) as applicable. For example, if the plan intends to cover the 3 tablet strengths of the brand product Valium as well as the generic equivalent Diazepam, then the plan should submit 3 records with the drug name "Valium" for each oral tablet strength and 3 records for each equivalent generic with the drug name "Diazepam". The plan should not submit

multiple NDCs representing alternative manufacturers of a drug. For example, providing only one proxy code for each dosage form, route and strength of the drug "Diazepam" is sufficient to represent any or all manufacturers of that generic drug entity.

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".TXT"

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NDC	CHAR Always Required	11	11-Digit National Drug Code	00000333800
Tier	CHAR Always Required	2	Defines the Cost Share Tier Level Associated with the drug. Assumption is that the drug is assigned to only one tier value. These values are consistent with the selection of tier level options available to data entry users in the Plan Benefit Package software.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6 7 = Tier Level 7 8 = Tier Level 8 9 = Tier Level 9 10 = Tier Level 10
Quantity_Limit_YN	CHAR Always Required	1	Does the drug have a quantity limit restriction?	0 = No Quantity Limits 1 = Quantity Limits Apply
Quantity_Limit_ Amount	NUM Sometimes Required	7	If Quantity_Limit_YN = 1 (Limits Apply), enter the quantity limit unit amount for a given prescription or time period. The units for this amount must be defined by a unit of measure e.g. number of tablets, milliliters, grams, etc. If the Quantity_Limit_YN = 0 (No Limits), leave this field blank. The maximum number of decimal points that will be accepted is 5., i.e., "9.99999." The maximum number that will be accepted is "9999.99."	9

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Quantity_Limit_Days	NUM Sometimes Required	3	Enter the number of days associated with the quantity limit. If the Quantity_Limit_YN field is 0 (No), then leave this field blank. The maximum logical number that will be accepted is “999”.	60 (e.g. 9 pills every 60 days)
Capped_Benefit_YN	CHAR Always Required	1	Does the drug have a capped benefit limit?	0 = No 1 = Yes
Capped_Benefit_ Quantity	NUM Sometimes Required	7	If Capped_Benefit_YN field is 1 = Yes, enter the capped benefit limit unit amount for a given prescription or time period. The units for this amount may be defined by a unit measure e.g. number of tablets, number of milliliters, number of grams, etc. If the Capped_Benefit_YN field is 0 = No, then leave this field blank The maximum logical number that will be accepted is “9999.99”.	365
Capped_Benefit_Days	NUM Sometimes Required	3	Enter the number of days associated with the capped benefit limit. If the Capped_Benefit_YN field is 0 = No, then leave this field blank The maximum logical number that will be accepted is “999”	365 (e.g. 365 tablets every 365 days)
Prior_Authorization_ YN	CHAR Always Required	1	Is prior authorization required for the drug?	1 = Yes 0 = No
Prior_Authorization_ Criteria	CHAR Sometimes Required	1500	The description of the drug’s prior authorization criteria. If response to	

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
			Prior_Authorization_YN = 0 (No), then leave this field blank.	
Step_Therapy_YN	CHAR Always Required	1	Does step therapy apply to this drug?	1 = Yes 0 = No
Step_Therapy_Desc	CHAR Sometimes Required	500	Description of step therapy. If response to Step_Therapy_YN = 0 (No), then leave this field blank.	

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

Also, please note that if you indicated "Yes" to Prior Authorization (PA) or Step Therapy (ST) for any of these excluded drugs you will explain the PA or ST criteria in text format within this file. There is not a separate PA or ST document for the excluded drugs and they should not be included on your formulary's PA and ST criteria documents.

OVER THE COUNTER RECORD LAYOUT

For each plan that provides Over the Counter Drugs as part of a drug utilization management program, the organization must submit a supplemental file that defines the covered drugs. The plan must choose their proxy NDC. The file must be created in an ASCII File format and contain one proxy NDC for each covered drug defined by the variables provided in the Over the Counter File Record Layout displayed. The plan should submit one record for each brand and equivalent generic drug product as applicable. For example, if the plan intends to pay for Claritin 10mg tablet as well as the generic equivalent Loratidine 10mg, then the plan should submit 1 record with the drug name "Claritin" for the oral tablet 10mg strength and 1 record for the equivalent generic with the drug name "Loratidine". The plan should not submit multiple NDCs representing alternative manufacturers of a drug. For example, providing only one proxy code for each dosage form, route and strength of the drug "Loratidine" is sufficient to represent any or all manufacturers of that generic drug entity. The plan should submit one proxy NDC for each brand product within the below format and one proxy NDC for each generic product within the below format.

Required File Format = ASCII File - Tab Delimited
Do not include a header record
Filename extension should be ".TXT"

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NDC	CHAR Always Required	11	11-Digit National Drug Code	00000333800

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), 3) semi-colon (;), and 4) ampersand (&).

APPENDIX C: FORMULARY UPLOAD AND SUPPLEMENTAL FILES EDIT RULES - CY 2010

This section provides a listing of validation edits that are performed when formulary files are uploaded and submitted to HPMS. This list is not all-inclusive but does include the vast majority of edit rules. These rules are included to assist you in troubleshooting your submissions should rejection errors occur.

There are two areas where the edit rules will take place:

a) On-line Upload
b) Formulary Validation Process

ON-LINE UPLOAD

The users will NOT be allowed to continue with the upload if any of the following edit checks fail:

1. The **Tier_Level** field must be filled and must be a valid number between 1 and 10.
2. On the **Drug Tier Information** page, both the **Specialty Tier and Preferred Tier** cannot both be answered "Yes" within a given tier.
3. On the **Drug Tier Information** page, only tiers with Anticipated Tier names of "Brand," "Preferred Brand," and "Other" may have the indicator of Preferred Tier.
4. On the **Drug Tier Information** page, a Preferred Tier may not be selected for "Non Preferred Brand" Drug Types.
5. The system will search for **HPMS restricted characters** (greater than >, less than <, semi-colon ;, and ampersand &) in the upload file and will **reject** submissions if the file contains one or more restricted characters.

FORMULARY VALIDATION PROCESS

An email will be sent to the person who uploaded the Formulary, as well as the Formulary Contact for each contract associated with the Formulary. This email will notify the user if the edit checks were successful and otherwise contain an error message for each edit check that did not pass. The edit checks are as follows:

1. The Formulary File must be **tab-delimited** and must **no**t contain **a header record.**
2. The **RxCUI, Tier_Level, Quantity_Limit_YN, Prior_Authorization_Type, Therapeutic_Category_Name, Therapeutic_Class_Name, Limited_Access_YN, Drug_Type_Label** and **Step_Therapy_Type** fields must be non-missing for submission.
3. The maximum value for **Tier_Level** field in the Formulary File must be equal to the number of cost share tiers entered in HPMS data entry.

4. The value of the **Tier_Level** must be 1 to 10.
5. There should be **at least one row** in the Formulary submission file for every tier identified on the **Formulary Tier Information** page.
6. The **Drug_Type_Label** must have a value of 1 to 6; it cannot be null.
7. In HPMS data entry, if the user selects **YES** on the **Limited Access question**, then one or more records in the Formulary File must have a **1 = YES** value for the **Limited_Access_YN** field in the Formulary File.
8. In HPMS data entry, if the user selects **NO** on the **Limited Access question**, then all records in the Formulary File must have a **0 = NO** value for the **Limited_Access_YN** field in the Formulary File.
9. The value of **Limited_Access_YN** field must be 0 or 1.
10. If the **Quantity_Limit_YN** is **1 = Quantity Limits Apply**, then the **Quantity_Limit_Amount** field must be a non-missing numeric value greater than 0 and less than 10,000 (.00001 to 9999.99). The field can have up to five decimal places (9.99999). The floor for entry is 0.00001. Possible entries include 9.99999 -> 99.9999 -> 999.999 -> 9999.99.
11. If the **Quantity_Limit_YN** is **1 = Quantity Limits Apply**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be a non-missing and must be a value of 1 - 999.
12. If the **Quantity_Limit_YN** is **0 = NO Quantity Limits**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be null.
13. The **Prior_Authorization_Type** field must be a value of 0 to 3.
14. In HPMS data entry, if the user selects **YES** to the **Prior Authorization question,** then one or more records in the Formulary File must have a value of 1 or greater for the **Prior_Authorization_Type** field in the Formulary File.
15. In HPMS data entry, if the user selects **NO** to the **Prior Authorization question,** then ALL records must have a value of **0 = NO Prior Authorization** for the **Prior_Authorization_Type** field in the Formulary File.
16. If the **Prior_Authorization_Type** field is **greater than 0,** then the **Prior_Authorization_Group_Desc** must be non-missing.
17. If the **Prior_Authorization_Type** field is equal to 0, then the **Prior_Authorization_Group_Desc** must be null.
18. For each **RxCUI** in the Formulary File with a **Prior_Authorization_Type = 1 or 2,** the **Prior_Authorization_Group_Desc** must exist in the Prior Authorization submission file.
19. In HPMS data entry, if the user selects **YES** to the **Step Therapy question**, then one or more records in the Formulary File must have a value **greater than 0** for the **Step_Therapy_Type** field in the Formulary File.
20. In HPMS data entry, if the user selects **NO** to the **Step Therapy question**, then ALL records must have a value of **0 = No Step Therapy Applies** for the **Step_Therapy_Type** field in the Formulary File.
21. In HPMS data entry, if the user selects **YES** to the **Quantity Limits question**, then one or more records in the Formulary File must have a value of **1 = Quantity Limits Apply** for the **Quantity_Limit_YN** field in the Formulary File.
22. In HPMS data entry, if the user selects **NO** to the **Quantity Limits question**, then ALL records must have a value of **0 = NO Quantity Limits** for the **Quantity_Limit_YN** field in the Formulary File.

23. If the **Step_Therapy_Type** is **greater than 0**, then the **Step_Therapy_Total_Groups** field must be non-missing.
24. If the **Step_Therapy_Type** is equal to **0**, then the **Step_Therapy_Total_Groups** field must be null.
25. The **Step_Therapy_Type** field must be a value of 0 to 2.
26. If the **Step_Therapy_Total_Groups** field is non-missing, it must be numeric, greater than 0 and less than 100 (1 to 99; whole numbers only).
27. If the **Step_Therapy_Step_Value** field is non-missing, it must be numeric, greater than 0 and less than 100 (1 to 99; whole numbers only).
28. If **Step_Therapy_Total_Groups** is non-missing, then the number of **pairs** of **Step_Therapy_Group_Desc** and **Step_Therapy_Step_Value** must equal the number indicated in **Step_Therapy_Total_Groups**.
29. If **Step_Therapy_Total_Groups** is null, then **Step_Therapy_Group_Desc and Step_Therapy_Step_Value** fields must be null.
30. If **Step_Therapy_Total _Groups** is non-missing, then **Step_Therapy_Step_Value and Step_Therapy_Group_Desc**, fields must be non-missing.
31. Check that for each **RxCUI**, the same **Step_Therapy_Group_Desc** does not occur more than once in the step therapy trailer.
32. For each **Step_Therapy_Group_Desc**, there must be at least one **RxCUI** with an associated **Step_Therapy_Step_Value** equal to 1 for that description and at least one **Step_Therapy_Step_Value** greater than 1 for that description.
33. If **Step_Therapy_Group_Desc** field is non-missing, ensure that the **Step_Therapy_Group_Desc** field is not greater than 100 characters in length.
34. Check the Formulary File's RxCUIs against the **RxCUI** in the **Formulary Reference File** to determine the validity of the RxCUIs in the Formulary File. This check should be performed for all initial submissions and resubmissions. If any RxCUIs do not match, then display an error message listing the Formulary File's RxCUIs that did not match with the table in the emails sent out to the Formulary Contacts.
35. The primary key of the submission file must be RxCUI alone.
36. Check for the submission of Gap Coverage, Free First Fill, and Home Infusion files. If this data has been uploaded, then validate the **RxCUIs** in the files against the relevant Formulary submission version. If an RxCUI exists in a **supplemental file** but not in the Formulary submission file, and then reject the supplemental file upload. If the data passes validation, then unload the data into the database.
37. The **maximum number** of errors that will be allowed before processing of the Formulary File stops will be **200**.
38. The **Formulary and dependent files** (Prior Authorization and/or Step Therapy files, if submitted) will **be rejected** if the validation does not meet these rules.

SUPPLEMENTAL FILES VALIDATION

Over the Counter Drug File:

1. The file must be in a **text** (.txt) format and must not contain a **header record.**
2. Each **NDC** must be unique in the submitted file, non-missing, and 11 characters in length.
3. The system will search for **HPMS restricted characters** (greater than >, less than <, semi-colon ;, and ampersand &) in the upload file and will reject submissions if the file contains one or more restricted characters.

Excluded Drug File:

4. The file must be in a **tab-delimited text** (.txt) format and must not contain a **header record.**
5. **Validate** the lengths and values for all fields (see file layout).
6. Each **NDC** must be unique in the submitted file, non-missing, and 11 characters in length.
7. Check the Excluded Drug File to ensure that the following fields are not null: **NDC, Tier, Quantity_Limits_YN, Capped_Benefit_YN, Prior_Authorization_YN, Step_Therapy_YN.**
8. For the Excluded Drug File, if **1 = YES** is entered for **Quantity_Limits_YN**, then **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be non-missing.
9. For the Excluded Drug File, if **0 = NO** is entered for **Quantity_Limits_YN,** then **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be null.
10. For the Excluded Drug File, if **1 = YES** is entered for **Capped_Benefit_YN**, then **Capped_Benefit_Quantity** and **Capped_Benefit_Days** must be non-missing.
11. For the Excluded Drug File, if **0 = NO** is entered for **Capped_Benefit_YN**, then **Capped_Benefit_Quantity** and **Capped_Benefit_Days** must be null.
12. For the Excluded Drug File, if **1 = YES** is entered for **Prior_Authorization_YN,** then **Prior_Authorizaion_Criteria** must be non-missing.
13. For the Excluded Drug File, if **0 = NO** is entered for **Prior_Authorization_YN**, then **Prior_Authorizaion_Criteria** must be null.
14. For the Excluded Drug File, if **1 = YES** is entered for S**tep_Therapy_YN**, then **Step_Therapy_Criteria** must be non-missing.
15. For the Excluded Drug File, if **0 = NO** is entered for **Step_Therapy_YN**, then **Step_Therapy_Criteria** must be null.
16. The system will search for **HPMS restricted characters** (greater than >, less than <, semi-colon ;, and ampersand &) in the upload file and will reject submissions if the file contains one or more restricted characters.

Gap Coverage, Free First Fill, Home Infusion Files:

17. The Home Infusion, Gap Coverage, and Free First Fill submissions must contain an **RxCUI** that exists in the Formulary Submission file.
18. Each **RxCUI** must be unique in the submitted file.
19. The system will search for **HPMS restricted characters** (greater than >, less than <, semi-colon ;, and ampersand &) in the upload file and will reject submissions if the file contains one or more restricted characters.

Prior Authorization File:

20. The file must be in a **tab-delimited text** (.txt) format and must not contain a **header record.**
21. **For the Prior Authorization File, check that all occurrences of the** Prior_Authorization_Group_Desc **field provided are unique and exist in the** Prior_Authorization_Group_Desc **field in the Formulary file. Both the Formulary and Prior Authorization files will be rejected if the validation does not pass.**
22. **For the Prior Authorization File, check that all unique occurrences of the** Prior_Authorization_Goup_Desc **field provided in the Prior Authorization File exist**

in the Prior_Authorization_Group_Desc **field in the submitted formulary. Both the Formulary and Prior Authorization files will be rejected if the validation does not pass.**

23. For the Prior Authorization File, the system will ensure that the **Prior_Authorization_Group_Desc, PA_Criteria_Change_Indicator, Covered_Uses,** and **Coverage_Duration** fields are not null.
24. The system will search for **HPMS restricted characters** (greater than >, less than <, semi-colon ;, and ampersand &) in the upload file and will reject submissions if the file contains one or more restricted characters.

Step Therapy File:

1. **The file must be in a** tab-delimited text **(.txt) format and must not contain a** header record.
2. **For the Step Therapy File, check that all occurrences of the** Step_Therapy_Group_Desc **field provided in the Step Therapy File are unique and exist in the** Step_Therapy_Group_Desc **field in the submitted Formulary.**
3. **For the Step Therapy File, the system will validate that the** Step_Therapy_Group_Desc **and the** Step_Therapy_Criteria **fields are non-missing.**
4. **The system will search for** HPMS restricted characters **(greater than >, less than <, semi-colon ;, and ampersand &) in the upload file and will reject submissions if the file contains one or more restricted characters.**

APPENDIX D: CONTACT INFORMATION

Contact	Phone Number	Email Address
HPMS Technical Help Desk	1-800-220-2028	hpms@cms.hhs.gov
HPMS		
Julia Heeter	410-786-6198	julia.heeter@cms.hhs.gov
Ana Nunez-Poole	410-786-3370	ana.nunezpoole@cms.hhs.gov
Formulary Content & Review Guidelines		
Brian Martin	410-786-1070	brian.martin@cms.hhs.gov
Kady Flannery	410-786-6722	kathleen.flannery@cms.hhs.gov
Supplemental Submissions and Reports		
Rosalind Abankwah	410-786-2012	rosalind.abankwah@cms.hhs.gov
Frank Tetkoski	410.786.5233	frank.tetkoski@cms.hhs.gov