HEALTH PLAN MANAGEMENT SYSTEM

FORMULARY SUBMISSION MODULE & REPORTS TECHNICAL MANUAL

MARCH 28, 2014

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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 Centers for Medicare & Medicaid Services (CMS) provided Formulary Reference File (FRF).

The purpose of the Formulary Submission Module & Reports Technical Manual is to provide step-by-step instructions on how to submit and revise plan formularies. It also provides instructions on:

- How to delete formularies no longer in use.
- How to submit and revise formulary transition policies.
- How to submit Pharmacy and Therapeutic (P&T) Committee Attestations.
- How to submit Prior Authorization and Step Therapy (PA/ST) Attestations.
- How to submit Medicare-Medicaid Plans (MMP) Additional Demonstration Drug (ADD) Files.
- How to submit supplemental files associated with a formulary
- Generate reports to monitor the status of formulary, supplemental and Additional Demonstration Drug submissions.

Key formulary submission enhancements for Contract Year (CY) 2015 are:
Medicare-Medicaid Plans (MMPs):
- MMP formularies have updated tier models from which to choose. The model selected in the formulary module must be consistent with the model selected in the Plan Benefit Package (PBP).
- MMP formulary files must include all Medicare tiers based on the tier model selected on the Formulary Tier Information page.
- ADD files must include all Non-Medicare tiers and combo tiers as defined in PBP for the selected MMP contract.
- State Reviewers are copied on the ADD file processing results email for ADD resubmissions.
- Ability to view MMP state from the MMP Submission Detail Report.

All Plans:
- Ability to reuse previously-submitted supplemental (Partial Gap, Free First Fill (FFF), or Home Infusion (HI)) files while accepting line level decisions.
- Formulary Contract Association Report is updated to exclude transition policy information.
- There is a new Formulary Transition Policy Report that provides information about Transition Attestation and Policy Status.

- Formulary Crosswalk Report is updated to exclude non-part D contract/plans. New 'Plan Type' column is added to the report.

The CY2015 HPMS Formulary Submission module is available to organizations on May 12th, 2014. CY2015 Formulary Submissions are due June 2, 2014 at 11:59pm Pacific Time (PT). It is highly recommended that organizations submit their formulary files as early as possible during the upload timeframe. Uploading earlier in this time frame provides organizations with adequate time to address potential upload problems and submit corrected formulary files before the deadline.

An organization may resubmit a formulary as many times as necessary during the initial upload period. Only the last successful submission will be processed for CMS review. Organizations using a formulary must provide a formulary file, along with the applicable supporting documentation (e.g., Prior Authorization attachment or Step Therapy attachment).

The CY2015 formulary supplemental submission window opens on or about June 4, 2014 to support the submission of Partial Gap Coverage, Free First Fill, Home Infusion, Over the Counter, Excluded Drug, and Additional Demonstration Drug supplemental files. Supplemental submissions are due by June 6, 2014, 12pm noon ET.

Organizations must submit supplemental information for all the plans offering this coverage as specified in the PBP submission. Only one version of a supplemental file may be submitted for each file type per formulary. Plans may only share a given formulary and supplemental file type (e.g., partial gap coverage file) provided that the content of the supplemental file type is applicable to all plans that share the file. Users may submit their supplemental files as many times as necessary during the initial upload period. Only the last successful submission is processed for CMS review. The supplemental files cannot be loaded until the organizations have successfully submitted their related bids (due June 2, 2014 by 11:59pm PT).

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

I. GETTING STARTED

ACCESSING HPMS

The HPMS Formulary Submission module is hosted on a secure site that you can access via the Internet.

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/InformationSecurity/Downloads/EUAaccessform.pdf

Complete the form as follows:
- Section 1 – Check "New" as the type of request.
- Section 2 – Check "Medicare Advantage / Medicare Advantage with Prescription Drug / Prescription Drug Plan / Cost Contracts – Using HPMS Only" and complete the data entry fields, where applicable.
- Section 3 – Enter the contract numbers for which you need access for CY2015.
- Section 4 – Check the first row beneath the "Default Non-CMS Employee" row (i.e., place a check in the Connect box of the third row). On the blank line beside your check mark, write "HPMS_P_CommlUser".
- Section 5 – State briefly why you require HPMS access.
- Section 6 – Leave blank.

Sign and date the Privacy Act Statement on page 3 of the form. Also enter your name and Social Security Number at the top of page 3. This step is critical to ensuring the successful processing of your request.

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 Numbers, and
- Contract Numbers to be added.

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

HOW TO ACCESS HPMS HOME PAGE USING THE INTERNET
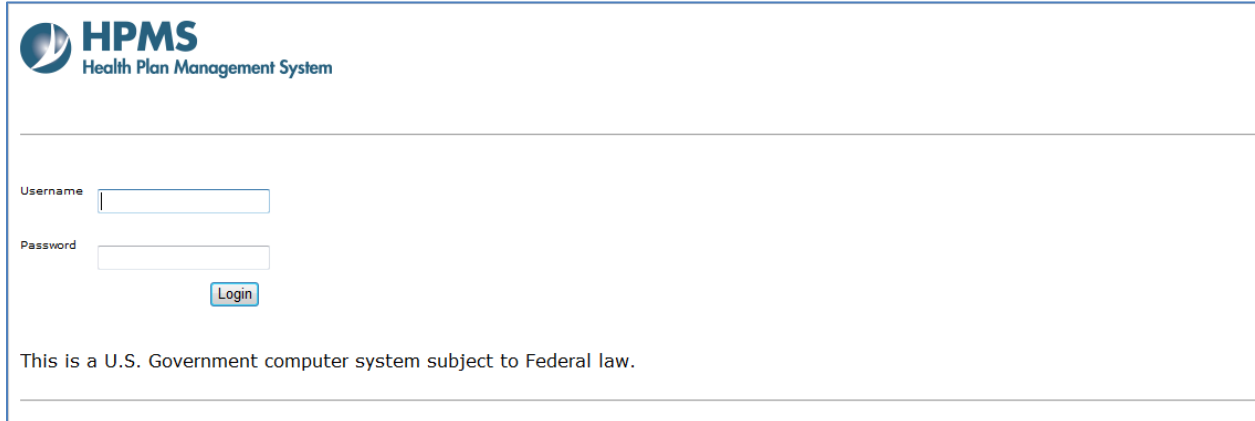
STEP 1
Open your web browser (e.g., Internet Explorer) and enter https://hpms.cms.gov in the Address bar.

STEP 2
Enter your CMS User ID and password and click the "Login" button (see Exhibit 1).

Exhibit 1 – HPMS Login

NAVIGATION

Enter the Formulary Submission module by selecting from the horizontal, top navigation bar: Plan Formularies, then Formulary Submission or Formulary Reports.

Once in the Formulary module, a collapsible navigation menu, on the right side of each page, provides links for each contract year that expand to provide the formulary submission functions or reports for each year.

As navigation progresses through formulary module, a breadcrumb trail displays starting from the left, beneath the top navigation menu. The trail tracks major milestones in navigation. Selecting a breadcrumb returns to that navigational milestone.

ACCESS HPMS FORMULARY SUBMISSION MODULE

STEP 1
To access the Formulary Submission Module, select **Plan Formularies** drop down from the HPMS top navigation bar. Then select the Formulary **Submission** menu item. (See Exhibit 2). This will take you to Formulary Submission Start Page.

Exhibit 2 – HPMS Home

STEP 2

On the Formulary Submission Start page, select the appropriate contract year from the collapsible navigation menu, on the right side of the page (see Exhibit 3). This will take you to the **Formulary Submission Start** page (see Exhibit 4).

Exhibit 3 – Formulary Submission Select Contract Year

Exhibit 4 – Formulary Submission Start Page

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 C provides a subset of validation rules for the formulary submission process.

The following functions are available from the right navigation menu of the CY2015 Formulary Submission Start page (see Exhibit 4)

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 reasons:
- The formulary requires resubmission because it was rejected by the validation process or desk review has requested resubmission.
- The formulary was previously approved by desk review and now needs to be updated.
- Revise PA/ST Criteria only (not the formulary) when the formulary was rejected by the validation process because of PA/ST validation errors or when CMS requested edits on existing criteria.

Delete Formulary: Delete a formulary that is no longer applicable.

Transition Policy: Submit Formulary Transition Policy and Attestation.

Revise Transition Policy: Revise and resubmit Formulary Transition Policy.

P & T Committee Attestation: Submit Pharmacy and Therapeutic (P&T) Committee Attestations.

PA/ST Attestation: Submit Prior Authorization and Step Therapy (PA/ST) Attestations

Submit Partial Gap Coverage File: Submit the Gap Coverage Supplemental Files for Formularies that include Gap Coverage.

Submit Free First Fill File: Submit the Free First Fill Supplemental Files for Formularies that include Free First Fill.

Submit Home Infusion File: Submit the Home Infusion Supplemental Files for Formularies that include Home Infusion.

Submit OTC File: Submit the OTC Supplemental Files for Formularies that include OTC.

Submit Excluded Drug File: Submit the Excluded Drug Supplemental Files for Formularies that include Excluded Drugs.

Submit MMP Additional Demonstration Drug File: Submit the Additional Demonstration Drug (ADD) Files for Medicare-Medicaid formularies only.

Documentation: Provides links to the following documents:
- **Formulary Instructions** – View the instructions for the Formulary Submission Module and Formulary Reports Manual.
- **Formulary Reference File** – Download a copy of the Reference File, Formulary Reference Change Report, and Contract Year Crosswalk File for current or upcoming contract year.
- **Submission File Layouts** – View formulary file, supplemental file, ADD and PA/ST file record layouts.
- **OMB Clearance** – View Office of Management and Budget (OMB) Clearance

II. SUBMIT NEW FORMULARY

The Submit New Formulary function is used to submit a new formulary. A new formulary may only be submitted during the initial formulary submission window. If you need to revise a previously submitted formulary, you should use the Revise Formulary function (refer to Chapter III).

When submitting a new formulary, you will:

1. **Select Formulary Plan Type** – Indicate whether you are a Medicare-Medicaid Plan.

2. **Associate Contracts to the Formulary** – Associate appropriate contracts with the formulary.

3. **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.

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

5. **Upload Files** – Upload the full Formulary file, Prior Authorization File (if required), and Step Therapy File (if required).

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

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

STEP 1
Select **Submit New Formulary** from the Formulary Submission Start page (see Exhibit 4). (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 Plan Type page.

FORMULARY PLAN TYPE

The **Formulary Plan Type** page will allow you to indicate whether you are Medicare-Medicaid Plan.

STEP 1
On the **Formulary Plan Type** page (see Exhibit 5), select 'yes' or 'no' to indicate whether you are a Medicare-Medicaid plan.

Exhibit 5 – Formulary Submission - Formulary Plan Type

Home » Formulary Submission » *CY 20XX* » *Submit New Formulary*

Formulary Submission - Formulary Plan Type

Formulary Submission   **+**

*Indicates required field.

*Are you a Medicare-Medicaid Plan?

○ Yes
○ No

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<u>STEP 2</u>

Click the "Next" button. This will take you to the Associate Contracts to Formulary page.

ASSOCIATE CONTRACTS TO FORMULARY

The **Associate Contracts to Formulary** page will allow you to associate contracts to the formulary submission.

In the previous step if you answered "Yes" for MMP, the system will display only MMP contracts for which you have access (See Exhibit 7). If you answered "No", the system will display all contracts other than MMP contracts for which you have access (See Exhibit 6).

<u>STEP 1</u>

On the **Associate Contracts to Formulary** page, 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.

Note: A formulary may only be associated with the contracts that belong to the same parent organization. If you select a contract with no parent organization, you will receive a warning message. Verify that all the contracts belong to the same parent organization before continuing with the submission.

Note: A specific Medicare-Medicaid Plan (MMP) formulary can be associated with only one MMP contract. MMP formularies cannot be shared across contracts.

Exhibit 6 – Formulary Submission - Associate Contracts to Formulary

Exhibit 7 – Formulary Submission - Associate MMP Contract to Formulary

STEP 2

Click the "Next" button to confirm the Contract Associations. This will take you to the Formulary Information page.

FORMULARY INFORMATION

The **Formulary Information** page collects information about your formulary submission including: the approved CY 2014 Formulary ID that closely resemble the current submission, Formulary Name, Formulary Classification System, Number of Tiers, OTC as part of a Step Therapy Protocol status, Quantity Limit status, Limited Access status, Prior Authorization status, and Step Therapy status.

STEP 1
On the **Formulary Information** page (see Exhibit 8), respond to the questions. With the exception of the question about which Approved CY 2014 Formulary ID closely resembles the current submission, all fields are required.

Note: When responding to the question about which Approved CY 2014 Formulary ID closely resembles the current submission, please be advised that you may identify a CY 2014 Formulary ID that was not associated with the contract in the previous year, as might be the case with MMPs, provided that it most closely resembles the formulary you are currently submitting.

Note: When defining the number of tiers, you may only define up to six tiers. MMP formularies can only have tiers 2-6. MMP users will be restricted from entering 1 in the Number of Tiers field.

STEP 2
Click the "Next" button to confirm your entries and move to the Formulary Tier Information page.

Exhibit 8 – Formulary Submission - Formulary Information

Formulary Submission - Formulary Information

Formulary Submission   +

*Indicates required field.

Please select the CY 2014 Formulary ID which most closely resembles this formulary submission.
   NOTE: CMS may utilize previously submitted clinical justifications and other formulary information relating to the CY 2014 formulary in its review of your CY 2015 submission.

CY 2014 Formulary: [▼]

*Formulary Name (max. 100 Characters): [   ]

   NOTE: This is a descriptive name you can use to help identify a formulary. This name can be as simple as Formulary 1, Formulary 2, etc.

   *Indicate the Formulary Classification System for this formulary: ○ **USP** ○ **AHFS** ○ **Other**

*Define number of Tiers (max. 6 tiers): [   ]

   NOTE: If all drugs are contained in a single tier, please enter '1' as the value for this field.
   Formularies that will **only** be associated with Defined Standard plans should be submitted as having a single tier.
   Please ensure this entry corresponds to the number of tiers to be entered in the Plan Benefit Package (PBP) software.

Formulary Effective Date: 1/1/2015

   *Do you offer OTCs as part of a Step Therapy Protocol submitted for review and approval by CMS?   ○ **Yes** ● **No**

   *Do any drugs in this formulary submission have Quantity Limits?   ○ **Yes** ○ **No**

   *Is access to any formulary drug restricted to certain pharmacies?   ○ **Yes** ○ **No**

   *Do any drugs in this formulary submission require Prior Authorization?   ○ **Yes** ○ **No**

   *Do any drugs in this formulary submission require Step Therapy?   ○ **Yes** ○ **No**

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FORMULARY TIER INFORMATION

The **Formulary Tier Information** page collects information about the tiers within the formulary. The page will automatically generate the tier models based on the information you entered on the Formulary Information page and whether or not you indicated that you were a Medicare-Medicaid Plan. Formularies that will only be associated with Defined Standard plans should be submitted as having a single tier. 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 2015 Plan Benefit Package (PBP) module, including plans offering an excluded drugs only tier (non-MMPs only).

Non-demonstration plans only: When developing the formulary tier structure, please use standard industry practices. Generally, Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. 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. However, please note that CMS implemented a formulary tier structure standardization to improve the comparability of plan offerings for beneficiaries. Therefore, CMS will allow a fifth or sixth tier that provides a meaningful benefit offering such as a $0 vaccine-only tier or a low or $0 cost-sharing tier for special needs plans (SNP) targeting specific conditions.

Note: Drop-down options for fifth and sixth tier formularies will include the following
- o Vaccines
- o Injectable tier
- o Specialty tier
- o Excluded drug only tier
- o Select diabetic drugs
- o Select care drugs

If a formulary includes an excluded drug only tier, no FRF drug should be entered on the formulary record layout as having that tier number.

Note: Based on the number of tiers defined in the formulary questions section, Tier Information Page displays pre-defined formulary tier models.

The tier models will be populated based on the plan type selected. MMP-specific tier models will be available for MMP formularies only. Non-MMP formularies will have regular tier models defined by CMS.

Although MMPs have the option to choose models ranging from 2-6 tiers, only Medicare tiers are included in the formulary file. Non-Medicare tiers are placeholder tiers for state-required drugs that are not covered under Part D. All non-Part D drugs required by the State are submitted on the Additional Demonstration Drug file the first week of June.

S̲TEP 1
On the **Formulary Tier Information** page (see Exhibit 9 and Exhibit 10) select a tier model appropriate for your formulary.

Exhibit 9 – Formulary Submission - Formulary Tier Information

Formulary Submission - Formulary Tier Information

Formulary Submission ✚

Select a Tier model from below options. Then select a Tier Label option from the drop down list when a drop down option is available.

NOTE: If a formulary includes a 5th or 6th tier that is an excluded drug only tier, NO FRF drug should be entered on the formulary record layout as having that tier number.
Excluded drugs will be entered on the excluded drug supplemental file that is submitted in conjunction with the bid in June.

6 Tier Model:

*Indicates required field.

*2015 Tier Model	TIER 1	TIER 2	TIER 3	TIER 4	TIER 5	TIER 6
◯	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Specialty Tier	Select a tier label ▼
◯	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Select a tier label ▼
◯	Preferred Generic	Non-Preferred Generic	Preferred Brand	Injectable Drugs	Specialty Tier	Select a tier label ▼
◯	Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Specialty Tier	Select a tier label ▼
◯	Preferred Generic	Preferred Brand	Non-Preferred Brand	Injectable Drugs	Specialty Tier	Select a tier label ▼

Dropdown options: Vaccines / Select Diabetic Drugs / Select Care Drugs / Excluded Drugs Only Tier / Select a tier label

[Back] [Next]

Exhibit 10 – Formulary Submission - MMP Formulary Tier Information

Formulary Submission - Formulary Tier Information

Formulary Submission ✚

Select a Tier model.

NOTE: The MMP formulary submission file should not include any Part D drugs on non-Medicare tiers.
All non-Medicare drugs must be entered in the Additional Demonstration Drug (ADD) file that is submitted in conjunction with bid in June.

6 Tier Model:

*Indicates required field.

*2015 Tier Model	TIER 1	TIER 2	TIER 3	TIER 4	TIER 5	TIER 6
◯	$0 Drugs	Preferred Generic	Non-Preferred Generic	Brand	Non-Medicare RX Drugs	Non-Medicare OTC Drugs
◯	$0 Drugs	Preferred Generic	Preferred Brand	Non-Preferred Brand	Non-Medicare RX Drugs	Non-Medicare OTC Drugs
◯	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Non-Medicare RX Drugs	Non-Medicare OTC Drugs
◯	$0 Drugs	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand	Non-Medicare Rx/OTC Drugs

[Back] [Next]

STEP 2

If your formulary includes two to four tiers, skip to Step 3.

If your formulary includes five or six tiers, select the fifth or sixth tier (see Exhibit 11), if applicable, from the drop down option.

STEP 3

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

Exhibit 11 – Formulary Submission - Formulary Tier Information

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 module will determine what you need to upload based on your responses on the Formulary Information page.

During initial submission, you will submit a full formulary file and full PA/ST files if applicable. After initial submission, your formulary and PA/ST files should only include changes only. To download all upload file, click the **Submission File Layouts** link in the Documentation section of the Formulary Submission Start Page.

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
  During the initial submission period, the value of the change_type field must be "ADD" for all records in the file.
  For more information/assistance on the Formulary file layout, see Appendices A and B in this Manual.
- **Prior Authorization File** – ASCII Tab delimited text file, e.g., *formularyPA*.txt
  During the initial submission period, the value of change_type field must be "ADD" for all records in the file.
  For more information/assistance on the Prior Authorization File, see Appendix B.
- **Step Therapy File** – ASCII Tab delimited text file, e.g., *steptherapy123ST*.txt
  During the initial submission period, the value of change_type field must be "ADD" for all records in the file.
  For more information/assistance on the Step Therapy File, see Appendix B.

STEP 1

On the **Upload Files** page (see Exhibit 12) 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 or location, click the "Browse" button to locate and attach the file.

Exhibit 12 – Formulary Submission - Upload Files

STEP 2A

Select the "Formulary includes Prior Authorization Type 3 drugs only" radio button if the formulary has PA Type 3 only. If this option is selected, no file upload is required. Skip to step 3.

STEP 2B

Select the "Select Prior Authorization File for Upload" radio button if the formulary has PA Type 1 or 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 the "Browse" button to locate and attach the file. (See Exhibit 12).

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 the "Browse" button to locate and attach the file. (See Exhibit 12).

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

STEP 4

Click 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.

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 (see Exhibit 13), review the information for accuracy.

STEP 2A
If any information is incorrect, click the "Back" button to correct the information as necessary.

STEP 2B
If all information is correct, click the "Submit" button to send the submission to CMS for review. This will take you to the Submission Confirmation page.

Exhibit 13 – Formulary Submission - Verify Submission

Formulary Submission - Verify Submission

Formulary Submission +

Formulary Name: Sample Formulary One
Formulary ID: 00000001
Formulary Version: 1

NOTE: Your data has not yet been submitted.

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
Contacts to be notified of this formulary submission:

Contact Type	User Id	Name	Email
Upload User	tstusr	Test User	Test.User@hpmstest.com
Z0001	n/a	SampleUser	SampleUser.One@hpmstest.com

Formulary Classification System used for this formulary: USP
Number of Tiers: 6

Tier Number	Tier Label
1	$0 Drugs
2	Preferred Generic
3	Non-Preferred Generic
4	Preferred Brand
5	Non-Preferred Brand
6	Non-Medicare Rx/OTC Drugs

Effective Date: 1/1/2015
Formulary offers OTCs as part of a Step Therapy Protocol: NO
Formulary includes drugs that have Quantity Limits: YES
Formulary includes drugs that are restricted to certain pharmacies: 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:\SampleFormulary.txt
Prior Authorization File	C:\SamplePA.txt
Step Therapy File	C:\SampleSTFile.txt

Back   Submit

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 all Formulary Contacts and the Formulary Upload Contact identified on this page acknowledging receipt of the submission and the assigned Formulary ID.

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

STEP 1
On the **Submission Confirmation** page (see Exhibit 14) review the information. As explained above, **MAKE NOTE OF YOUR ASSIGNED FORMULARY ID**.

STEP 2
Click 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, HPMS will perform a series of validation edits. At the close of the validation process, a follow-up email will be sent to the designated formulary contacts. This email will indicate that the formulary was successfully validated or 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 it using your assigned Formulary ID under the Revise Formulary function (refer to Chapter III).

Exhibit 14 – Formulary Submission - Confirm Submission

Home » Formulary Submission » CY 2015 » *Confirm Formulary*

Formulary Submission - Confirm Submission

Formulary Submission ＋

Formulary Name: Sample Formulary One
Formulary ID: 00000001
Formulary Version: 1

Your formulary information was received. The formulary contacts listed below will receive an email that the formulary submission was received.

The HPMS will now perform a series of validation edits on the formulary submission. At the close of the validation process, a second email will be sent to the formulary contacts listed below. This email will either indicate a successful formulary upload or identify the errors detected during validation. If errors were detected, the formulary submission will be rejected. Once the errors are corrected, the formulary can be resubmitted.

Contacts notified of this formulary submission:

Contact Type	User Id	Name	Email
Upload User	testuser	Test User	Sample.User@hpmstest.com
Z0001	n/a	SampleUser	SampleUserTwo@hpmstest.com

OK

III. REVISE FORMULARY

The **Revise Formulary** functionality is used to update formularies and the necessary PA and/or ST files (if applicable) that have already been submitted to CMS via HPMS. This functionality can also be used to update a formulary and PA or ST files before the initial submission deadline. You are only permitted to update a formulary and PA or ST files 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.

During initial submission, you can replace full files for the formulary, PA and ST files.

After the initial submission period, you will upload only changes to the formulary, PA and ST files (i.e., partial files) on the Revise Formulary page. If you are only making changes to your PA/ST criteria, you do not need to upload a formulary file.

After Bid submission, the **Revise Formulary** functionality may also be used to update certain existing supplemental files (if applicable), by indicating if the formulary with an associated Partial Gap Coverage, Free First Fill or Home Infusion supplemental file requires a change to the previously uploaded supplemental file or to continue using the previously uploaded supplemental file. This functionality is only available if your Bid has passed all validation checks and has been "Sent to Desk Review (DR)". You can check the current status of your Bid by reviewing the Bid Status History Report. The latest associated Partial Gap Coverage, Free First Fill, or Home Infusion supplemental file must also be in the "In Desk Review" or "Approved" status.

DETERMINE YOUR FORMULARY SUBMISSION STATUS

As shown in Exhibit 4, 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 "Access HPMS Formulary Submission Module" in Chapter I). This will take you to the Formulary Resubmission-Select a Formulary page.

The Formulary Resubmission–Select a Formulary page (See Exhibit 4) group's formularies into two categories:

> Resubmission/Updates – Formularies that are eligible for resubmission either due to a validation failure or because a reviewer requested a resubmission. Formularies that are approved by CMS and are available for update will be available in this category. This group also includes formularies eligible for resubmission during a scheduled window.

> In Process – Formularies that are in desk review.

Within each category, there 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 limited update window, formularies eligible for resubmission during the gate opening will show an "Approved" status.

In the Resubmission/Update category, there is a table listing columns entitled "Revise Formulary & PA/ST" and "Revise PA/ST Only".
If you are updating the formulary file, click the formulary ID hyperlink in the "Revise Formulary & PA/ST" column. This will allow you to upload changes to the formulary file as well as changes to the PA/ST Criteria files.

If you are updating the PA/ST Criteria files only, click the formulary ID hyperlink in the "Revise PA/ST Only" column.

Hyperlinks in these columns will be enabled under the following situations.

Revise Formulary & PA/ST: Hyperlinks in this column will be enabled when the formulary is in the status of "Resubmission Requested", "Rejected by Validation", or "Approved". You may upload a new version of the formulary and PA/ST files by selecting this hyperlink. If CMS requested resubmission through the Line Level Decision process by partially approving the submitted changes, selecting this hyperlink will navigate you to the Plan Line Level Decisions Accept/Reject page.

Revise PA/ST Only: Hyperlinks in this column will be enabled when the formulary is rejected because of PA/ST errors (or) when there are open edit requests. Selecting a hyperlink will navigate you to Revise PA/ST Criteria Upload page.

Exhibit 15 – Formulary Resubmission - Select a Formulary

Formulary Resubmission - Select a Formulary

| Formulary Submission | + |

These formularies are available for selection. TO VIEW THE STATUS OF ALL VERSIONS OF A FORMULARY, PLEASE UTILIZE THE FORMULARY STATUS HISTORY REPORT.

Resubmissions/Updates

Revise Formulary & PA/ST: You may upload a new version of the formulary by selecting the Formulary ID hyperlink in the Revise Formulary and PA/ST column. You will be able to make changes to the PA/ST criteria as well. If CMS requested resubmission by partially approving the submitted changes, selecting this Formulary ID hyperlink will navigate you to the Plan Line Level Decisions Accept/Reject page. This Formulary ID hyperlink is only available when the formulary gates are open.

Revise PA/ST Only: If there are no formulary updates to make, you may correct the PA/ST edits/errors by selecting the Formulary ID hyperlink located in the Revise PA/ST Only column. This Formulary ID hyperlink is only available when there are PA/ST errors and/or open edit requests.

Revise Formulary & PA/ST	Revise PA/ST Only	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000032-RF	00000032-PA/ST	Sample Formulary	2	Approved	Z0001	
00000012-RF	N/A	Sample Formulary Two	1	Rejected by Validation	Z0002	
00000014-RF	00000014-PA/ST	Sample Formulary Three	1	Rejected by Validation	Z0003	

In Process

These formularies are currently unavailable for revision.

Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000005	Sample Formulary Four	11	In Desk Review	Z0004	
00000007	Sample Formulary Five	5	In Desk Review	Z0005	

Back

REVISE FORMULARY & PA/ST

STEP 1
Select **Revise Formulary** from the **Formulary Submission Start** page. This will take you to the Formulary Resubmission - Select a Formulary page.

STEP 2A
On the **Formulary Resubmission - Select a Formulary** page (see Exhibit 15), select "Revise Formulary & PA/ST" hyperlink for the formulary you wish to update. 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 (see Exhibit 16) 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.

On the **Formulary Resubmission - Associate Contracts to Formulary** page (see Exhibit 16), select one or more of the contracts listed on the page to associate with the formulary.

Note: A formulary may only be associated to the contracts that belong to the same parent organization. If you select a contract with no parent organization, you will receive a warning message. Verify that all the contracts belong to the same parent organization before continuing with the submission.

Exhibit 16 – Formulary Resubmission - Associate Contracts to Formulary

STEP 2

On the **Formulary Resubmission - Associate Contracts to Formulary** page, click the "Next" button to confirm the Contract Associations (see Exhibit 16). This will take you to the Formulary Resubmission - Formulary Information page.

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:
- Prior Year Formulary

- Formulary Classification System, and
- Number of Tiers.

STEP 1

On the **Formulary Resubmission - Formulary Information** page (see Exhibit 17), enter any changes to the answers previously provided.

Exhibit 17 – Formulary Resubmission - Formulary Information

STEP 2

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

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 approved.

<u>STEP 1</u>
On the **Formulary Tier Information** page (see Exhibit 18) select a tier model appropriate for your formulary. MMPs will have a similar screen.

<u>STEP 2</u>
If your formulary includes 2-4 tiers, skip to Step 3.

If your formulary includes 5 or 6 tiers, select a drop-down option for 5th or 6th tier (Exhibit 19, non-MMP models) if applicable.

<u>STEP 3</u>
Click the "Next" button to confirm your information and move to the Upload Files page.

Note: Note that the tier information entered in the formulary submission module must correspond to the number of tiers and model that will be identified in the corresponding CY 2015 PBP software.

Exhibit 18 – Formulary Resubmission - Formulary Tier Information

Home » Formulary Submission » CY 2015 » Formulary Tiers

Formulary Resubmission - Formulary Tier Information | Formulary Submission | +

Formulary Name: Sample Formulary
Formulary ID: 00000032
Formulary Version: 2

Select a Tier model.

NOTE: The MMP formulary submission file should not include any Part D drugs on non-Medicare tiers.
All non-Medicare drugs must be entered in the Additional Demonstration Drug (ADD) file that is submitted in conjunction with bid in June.

4 Tier Model:

*Indicates required field.

*2015 Tier Model	TIER 1	TIER 2	TIER 3	TIER 4
⦿	Preferred Generic	Non-Preferred Generic	Preferred Brand	Non-Preferred Brand
○	Generic	Preferred Brand	Non-Preferred Brand	Non-Medicare Rx/OTC Drugs
○	Preferred Generic	Non-Preferred Generic	Brand	Non-Medicare Rx/OTC Drugs
○	$0 Drugs	Generic	Brand	Non-Medicare Rx/OTC Drugs
○	Generic	Brand	Non-Medicare Rx Drugs	Non-Medicare OTC Drugs

Back   Next

Exhibit 19 – Formulary Resubmission - Formulary Tier Information

UPLOAD FILES

The **Formulary Resubmission - Upload Files** page allows you to upload revised formulary, PA and ST files.

Following Bid submission, the **Formulary Resubmission - Upload Files** page will also allow you to indicate if the associated Partial Gap Coverage, Free First Fill, or Home Infusion files (if applicable) require or not require a change to the previous successfully-validated supplemental file.

During initial submission, you can replace full files for the formulary, PA and ST files. After the initial submission period, your upload files will include only the changes to your formulary, PA and ST files

Click the "Click here to view the Formulary File Upload Instructions" hyperlink (see Exhibit 20), to view the detailed instructions.

The files you are uploading must be in the following formats:

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

During the initial submission period, the value of this field must be "ADD" for all records in the file. After the initial submission period, the Partial formulary file may include a value of "ADD", "UPD", or "DEL" in the change type field.

For more information/assistance on the Formulary file layout, see Appendices A and B in this Manual.

- **Prior Authorization File** (applicable if the Initial Submission window is open) – ASCII Tab delimited text file, e.g., *formularyPA*.txt

    During the initial submission period, the value must be "ADD" for all records in the file. After the initial submission period, the partial PA file may include a value of "ADD", "UPD".

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

- **Step Therapy File** (applicable if the Initial Submission window is open) – ASCII Tab delimited text file, e.g., *steptherapy123ST*.txt

    During the initial submission period, the value must be "ADD" for all records in the file. After the initial submission period, the partial ST file may include a value of "ADD", "UPD".

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

STEP 1
On the **Formulary Resubmission - Upload Files** page (see Exhibit 20), 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 or location, click the "Browse" button to locate and attach the file.

Note: If your formulary is associated with a Partial Gap Coverage, Free First Fill, or Home Infusion supplemental file, follow steps 2-4 unless you failed to submit your required supplemental file(s) in your prior monthly update. In this case, the options to reuse or submit a new file will not be available to you at this time. You must return to the submission module following the successful validation of your formulary to submit your supplemental files. You may submit these files using the Submit Home Infusion File, Submit Free First Fill File, or Submit Partial Gap Coverage File options on the Formulary Submission Start page. Failure to upload the required supplemental files may result in suppression in Medicare Plan Finder.

STEP 2A
Select the "This Formulary does not require changes to the previously uploaded copy of the Partial Gap Coverage Supplemental File" option if no changes are required to the previous uploaded Partial Gap Coverage file against the revised formulary (if applicable). See Exhibit 20.

STEP 2B
Select the "This Formulary requires changes to the Partial Gap Coverage Supplemental File" option if changes are required to the previous uploaded Partial Gap Coverage file against the revised formulary (if applicable). See Exhibit 20.

Note that you must upload your Partial Gap Coverage supplemental file through the HPMS Submit Partial Gap Coverage File option on the Formulary Submission Start page after your formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your formulary, skip to step 5.

STEP 3A
Select the "This Formulary does not require changes to the previously uploaded copy of the Free First Fill Supplemental File" option if no changes are required to the previous uploaded Free First Fill file against the revised formulary (if applicable). See Exhibit 20.

STEP 3B
Select the "This Formulary requires changes to the Free First Fill Supplemental File" option if changes are required to the previous uploaded Free First Fill file against the revised formulary (if applicable). See Exhibit 20.

Note that you must upload your Free First Fill supplemental file through the HPMS Submit Free First Fill File option on the Formulary Submission Start page after your formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your formulary, skip to step 5.

STEP 4A
Select the "This Formulary does not require changes to the previously uploaded copy of the Home Infusion Supplemental File" option if no changes are required to the previous uploaded Home Infusion file against the revised formulary (if applicable). See Exhibit 20.

STEP 4B
Select the "This Formulary requires changes to the Home Infusion Supplemental File" option if changes are required to the previous uploaded Home Infusion file against the revised formulary (if applicable). See Exhibit 20.

Note that you must upload your Home Infusion supplemental file through the HPMS Submit Home Infusion File option on the Formulary Submission Start page after your formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your formulary, skip to step 5.

STEP 5A
Select the "Formulary includes Prior Authorization Type 3 drugs only" radio button if the formulary has PA type 3 only. If this option is selected, no file upload is required. Skip to step 6. See Exhibit 20

S**TEP** **5B**
Select the "Use previously uploaded copy of the Prior Authorization File" if you are not making any changes to your prior authorization criteria. See Exhibit 20.

S**TEP** **5C**
Select the "Select Prior Authorization File for Upload" radio button if the formulary has PA Type 1 or 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 the "Browse" button to locate and attach the file. See Exhibit 20.

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

After the initial submission period, the Partial PA file may include a value of "ADD" when a PA Group Description is added to the formulary or "UPD" when CMS has requested a change to the PA criteria. The system will automatically delete any PA Group Descriptions from the PA file that are not in the formulary.

S**TEP** **6A**
Select "Use previously uploaded copy of the Step Therapy File" if you are not making any changes to your step therapy criteria. See Exhibit 20.

S**TEP** **6B**
Enter the full path and name of the Step Therapy File (Tab delimited .txt file only) in the "Step Therapy File" field or click the "Browse" button to locate and attach the file. (See Exhibit 20).

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

After the initial submission period, the Partial ST file may include a value of "ADD" when an ST Group Description is added to the formulary or "UPD" when CMS has requested a change to the ST criteria. The system will automatically delete any ST Group Descriptions from the ST file that are not in the formulary.

Note: You will receive an email communication from CMS when PA/ST edits are requested on the Group Descriptions that require criteria updates.

S**TEP** **7**
Click 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. See Exhibit 20.

Exhibit 20 – Formulary Resubmission - Upload Files

Home » Formulary Submission » CY 20XX » *Upload Files*

Formulary Resubmission - Upload Files

Formulary Submission ✚

Formulary Name: Sample Formulary
Formulary ID: 00000032
Formulary Version: 2

*Indicates required field.

Click here to view Formulary File Upload Instructions

*FORMULARY FILE
Select Formulary File for upload: [   ] Browse...

*PARTIAL GAP COVERAGE SUPPLEMENTAL FILE

   ○ This Formulary does not require changes to the previously uploaded copy of the Partial Gap Coverage Supplemental File.
   ○ This Formulary requires changes to the Partial Gap Coverage Supplemental File.

*FREE FIRST FILL SUPPLEMENTAL FILE

   ○ This Formulary does not require changes to the previously uploaded copy of the Free First Fill Supplemental File.
   ○ This Formulary requires changes to the Free First Fill Supplemental File.

*HOME INFUSION SUPPLEMENTAL FILE

   ○ This Formulary does not require changes to the previously uploaded copy of the Home Infusion Supplemental File.
   ○ This Formulary requires changes to the Home Infusion Supplemental File.

*PRIOR AUTHORIZATION FILE

   ○ Formulary includes Prior Authorization Type 3 drugs only (no upload required)
   ○ Use previously uploaded copy of the Prior Authorization File View Previous Prior Authorization File
   ○ Select Prior Authorization File for upload: [   ] Browse...

*STEP THERAPY FILE

   ○ Use previously uploaded copy of the Step Therapy File View Previous Step Therapy File
   ○ Select Step Therapy File for upload: [   ] Browse...

[Back] [Upload]

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.

<u>STEP 1</u>
On the **Formulary Resubmission - Verify Resubmission** page (see Exhibit 21), review the information for accuracy.

Exhibit 21 – Formulary Resubmission - Verify Submission

Formulary Resubmission - Verify Submission

Formulary Submission +

Formulary Name: Sample Formulary
Formulary ID: 00000032
Formulary Version: 2

NOTE: Your data has not yet been submitted.

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: Z0002
Contacts to be notified of this formulary submission:

Contact Type	User Id	Name	Email
Upload User	tstusr	Test User	Test.User@hpmstest.com
Z0002	n/a	Test User2	Test.User2@hpmstest.com

Formulary Classification System used for this formulary: USP
Number of Tiers: 5

Tier Number	Tier Label
1	Generic
2	Preferred Brand
3	Non-Preferred Brand
4	Specialty Tier
5	Vaccines

Effective Date: 1/1/2014
Formulary offers OTCs as part of a Step Therapy Protocol: NO
Formulary includes drugs that have Quantity Limits: YES
Formulary includes drugs that are restricted to certain pharmacies: 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:\BDCLoad\FR4TNYYYY.txt
Prior Authorization File	C:\BDCLoad\PA.txt
Step Therapy File	C:\BDCLoad\ST.txt

Back   Submit

STEP 2A
If any information is incorrect, click the "Back" button to correct the information as necessary by returning to the appropriate pages.

STEP 2B
If all information is correct; click the "Submit" button to send the resubmission to CMS for review. This will take you to the Formulary Resubmission – Confirm Submission page.

CONFIRM SUBMISSION

The **Formulary Resubmission - Confirm Submission** 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 - Confirm Submission** page (see Exhibit 22) review the information. Click the "OK" button to return to the Formulary Submission Start Page.

Exhibit 22 – Formulary Resubmission - Confirm Submission

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, HPMS will perform a series of validation edits. At the close of the validation process, a follow-up email will be sent to the designated formulary contacts. This email will indicate that the formulary was successfully validated or identify errors detected during the validation process. If errors were detected, the formulary resubmission will be rejected.

Note: If the reused supplemental file is not sync with the new formulary version, the supplemental file will be rejected by validation and validation errors are sent in a separate email (if applicable).

REVISE PA/ST CRITERIA ONLY

During the Formulary Review period (initial review and monthly update), if there are PA/ST file errors on your formulary and PA/ST files you submitted previously, you will receive an ACTION REQUIRED email with the PA/ST Group Descriptions that require addition or criteria update. You will be required to upload a PA/ST file using the **Revise PA/ST Criteria** page. When you have successfully uploaded all the required changes, you will receive the formulary successfully validated email.

Note that any PA/ST Group Descriptions that are removed from the formulary will automatically be deleted from the PA/ST file. You will receive a confirmation of these deletions in the "Formulary – Processing Results" email.

In addition to this, CMS may request revision to specific Group Descriptions. You will receive an email from CMS directing you to change your PA/ST criteria. If you are making changes to the PA/ST files only, and not the formulary file, you may go directly to the Revise PA/ST Criteria page and upload your changes. The record format is the same as for the initial upload. You may only upload changes for the records that display on the page. The changes will be applied to the last version in desk review that is not Denied or Withdrawn. **If you are also making changes to your formulary, you must upload the formulary and PA/ST files together by selecting "Revise Formulary & PA/ST files" option on the Revise Formulary page.** After the files are successfully validated, the new version will be migrated to desk review.

In summary, you may go to the **Revise PA/ST Criteria** page to update PA/ST criteria and make the following changes:
- Add a PA/ST record when the PA/ST Group Description is in the formulary file and not in the PA/ST file
- Update a PA/ST record when requested by CMS.

As shown in Exhibit 23, click the "**Revise PA/ST Criteria Only**" hyperlink from the Formulary Resubmission – Select a Formulary page. This will take you to the Revise PA/ST Criteria – Upload page (See Exhibit 24).

Exhibit 23 – Formulary Resubmission - Select a Formulary

Formulary Resubmission - Select a Formulary

Formulary Submission ➕

These formularies are available for selection. TO VIEW THE STATUS OF ALL VERSIONS OF A FORMULARY, PLEASE UTILIZE THE FORMULARY STATUS HISTORY REPORT.

Resubmissions/Updates

Revise Formulary & PA/ST:	You may upload a new version of the formulary by selecting the Formulary ID hyperlink in the Revise Formulary and PA/ST column. You will be able to make changes to the PA/ST criteria as well. If CMS requested resubmission by partially approving the submitted changes, selecting this Formulary ID hyperlink will navigate you to the Plan Line Level Decisions Accept/Reject page. This Formulary ID hyperlink is only available when the formulary gates are open.
Revise PA/ST Only:	If there are no formulary updates to make, you may correct the PA/ST edits/errors by selecting the Formulary ID hyperlink located in the Revise PA/ST Only column. This Formulary ID hyperlink is only available when there are PA/ST errors and/or open edit requests.

Revise Formulary & PA/ST	Revise PA/ST Only	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000032-RF	00000032-PA/ST	Sample Formulary	2	Approved	Z0001	
00000012-RF	N/A	Sample Formulary Two	1	Rejected by Validation	Z0002	
00000014-RF	00000014-PA/ST	Sample Formulary Three	1	Rejected by Validation	Z0003	

In Process

These formularies are currently unavailable for revision.

Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000005	Sample Formulary Four	11	In Desk Review	Z0004	
00000007	Sample Formulary Five	5	In Desk Review	Z0005	

Back

Only the records that are displayed on the page may be submitted in the update file. The records should be in the same format as the initial PA/ST submission file. The system will only permit the action displayed on the page.

ADD: You must add a PA/ST record when you add a PA/ST Group Description to the formulary.

UPD – You must update a PA/ST record already existing on the approved file; the system only permits the following actions:

- You must update a PA/ST record when requested by CMS.
- At least one field should be changed for the update to be successful.

Note: You should not update the PA/ST record if you are deleting the PA/ST Group Description from your formulary. The system will automatically delete the PA/ST Group Description from the PA/ST file when it is removed from the formulary file.

REVISE PA/ST CRITERIA – UPLOAD

The **Revise PA/ST Criteria – Upload** page allows you to specify the Prior Authorization File and Step Therapy File you want to upload. The page will pre-determine what you need to upload based on formulary validation errors or CMS revision requests. This page displays PA and ST Group Descriptions that need to be added based on the formulary file submission. This includes:

- PA/ST Group Descriptions that were added to your formulary
- PA/ST Group Descriptions that were uploaded on the revise formulary page but failed validation
- PA and ST Group Descriptions requiring revision based upon CMS review

This page also displays links to current PA/ST criteria associated with the latest version of the formulary that is successfully sent to desk review and are not denied or withdrawn.

Exhibit 24 – Revise PA/ST Criteria - Upload

Only the records that are available on the page should be included in the partial file. Records with the Type of Action of "Edit" should have at least one field other than the Group Description updated in order to pass validation.

Both PA/ST files must be uploaded at the same time. If at least one file fails, both files will be rejected. After correcting the errors, both files must be uploaded again.

<u>STEP 1</u>

Enter the full path and name of the Prior Authorization File (tab delimited .txt file only) in the Step Therapy File field or click the "Browse" button to locate and attach the file. (See Exhibit 24.)

Note: If there were no Prior Authorization file errors during formulary revision or no pending CMS revision requests, this field will not be displayed.

<u>STEP 2</u>

Enter the full path and name of the Step Therapy File (tab delimited .txt file only) in the Step Therapy File field or click the "Browse" button to locate and attach the file. (See Exhibit 24.)

Note: If there were no Step Therapy file errors during formulary revision and no pending CMS revision requests, this field will not be displayed.

<u>STEP 3</u>

Click the "Upload" button to submit your files. This will take you to the Submission Confirmation page (see Exhibit 25).

SUBMISSION CONFIRMATION

The **Revise PA/ST Criteria - Confirm Submission** page provides confirmation on validity of the files (see Exhibit 25). If the files fail validation, an email with the subject "Formulary- Action Required" is sent to the Formulary Contacts listed on the page. If the files are successful formulary contacts will receive "Formulary- Processing Results" email. If only edits are submitted without resubmitting the formulary, you will receive an email with the subject "PA/ST Successful Upload - HPMS Formulary Upload XXXXXXXX-7".

Exhibit 25 – Revise PA/ST - Confirmation

On the Revise PA/ST Criteria – Confirm Submission page (see Exhibit 25), review the information. Click the "OK" button to return to the Revise PA/ST Criteria – Select Formulary page.

At this point, you have finished resubmitting your new formulary or PA/ST criteria revision.

IV. ACCEPT/REJECT LINE LEVEL CHANGES

CMS may find that your formulary revision is partially acceptable. When this is the case, you will receive a resubmission request for your formulary. When you select the formulary from the Revise Formulary page, you will be directed to the Accept Line Level Decisions page. You may review the CMS decisions, and then confirm your acceptance. This creates a new version of the formulary.

ACCESS TO THE LINE LEVEL DECISIONS PAGE

The system will automatically direct you to the Plan Line Level Decisions Accept/Reject page when you select a formulary for revision.

STEP 1
Select **Revise Formulary** from the Formulary Submission Start page (see Exhibit 4). This will take you to the Select a Formulary page.

STEP 2
On the **Formulary Resubmission - Select a Formulary** page (see Exhibit 26), click the "Revise Formulary & PA/ST" hyperlink for the formulary to review. This will take you to the Plan Line Level Decision Accept/Reject page (see Exhibit 27).

Exhibit 26 – Revise Formulary- Select a Formulary Page

Formulary Resubmission - Select a Formulary

Formulary Submission ➕

These formularies are available for selection. TO VIEW THE STATUS OF ALL VERSIONS OF A FORMULARY, PLEASE UTILIZE THE FORMULARY STATUS HISTORY REPORT.

Resubmissions/Updates

Revise Formulary & PA/ST:	You may upload a new version of the formulary by selecting the Formulary ID hyperlink in the Revise Formulary and PA/ST column. You will be able to make changes to the PA/ST criteria as well. If CMS requested resubmission by partially approving the submitted changes, selecting this Formulary ID hyperlink will navigate you to the Plan Line Level Decisions Accept/Reject page. This Formulary ID hyperlink is only available when the formulary gates are open.
Revise PA/ST Only:	If there are no formulary updates to make, you may correct the PA/ST edits/errors by selecting the Formulary ID hyperlink located in the Revise PA/ST Only column. This Formulary ID hyperlink is only available when there are PA/ST errors and/or open edit requests.

Revise Formulary & PA/ST	Revise PA/ST Only	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000032-RF	00000032-PA/ST	Sample Formulary	2	Approved	Z0001	
00000012-RF	N/A	Sample Formulary Two	1	Rejected by Validation	Z0002	
00000014-RF	00000014-PA/ST	Sample Formulary Three	1	Rejected by Validation	Z0003	

In Process

These formularies are currently unavailable for revision.

Formulary ID	Formulary Name	Version	Submission Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000005	Sample Formulary Four	11	In Desk Review	Z0004	
00000007	Sample Formulary Five	5	In Desk Review	Z0005	

Back

PLAN LINE LEVEL DECISIONS ACCEPT/REJECT

The **Plan Line Level Decisions Accept/Reject** page displays the RxCUI, Change Type, Brand Name, SCDC, and Dose Form for each drug in your formulary revision file, as well as the associated CMS decision. The page also provides links to the Non-Allowable Change Report and the Update Outlier Report for the submitted version of the formulary. When you accept the changes, the system will create a new version of the formulary that includes only the approved changes. You will not need to upload another revision file.

Exhibit 27 – Plan Line Level Decision Accept/Reject

Note: If your formulary is associated with a Partial Gap Coverage, Free First Fill, or Home Infusion supplemental file, follow steps 1-3 unless you failed to submit your required supplemental file(s) in your prior monthly update. In this case, the options to reuse or submit a new file will not be available to you at this time. You must return to the submission module following the successful validation of your formulary to submit your supplemental files. You may submit these files using the Submit Home Infusion File, Submit Free First Fill File, or Submit Partial Gap Coverage File options on the Formulary Submission Start page. Failure to upload the required supplemental files may result in suppression in Medicare Plan Finder.

<u>STEP 1A</u>

Select the "This Formulary does not require changes to the previously uploaded copy of the Partial Gap Coverage Supplemental File" option if no changes are required to the previously-uploaded Partial Gap Coverage file with respect to the revised formulary (if applicable). See Exhibit 27.

<u>STEP 1B</u>

Select the "This Formulary requires changes to the Partial Gap Coverage Supplemental File" option if changes are required to the previously-uploaded Partial Gap Coverage file with respect to the revised formulary (if applicable). See Exhibit 27

Note that you must upload your Partial Gap Coverage supplemental file using the HPMS Submit Partial Gap Coverage File option on the Formulary Submission Start page after your formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your formulary, skip to step 4.

<u>STEP 2A</u>

Select the "This Formulary does not require changes to the previously uploaded copy of the Free First Fill Supplemental File" option if no changes are required to the previously-uploaded Free First Fill file with respect to the revised formulary (if applicable). See Exhibit 27

<u>STEP 2B</u>

Select the "This Formulary requires changes to the Free First Fill Supplemental File" option if changes are required to the previously-uploaded Free First Fill file with respect to the revised formulary (if applicable). See Exhibit 27.

Note that you must upload your Free First Fill supplemental file using the HPMS Submit Free First Fill File option on the Formulary Submission Start page after your formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your formulary, skip to step 4.

<u>STEP 3A</u>

Select the "This Formulary does not require changes to the previously uploaded copy of the Home Infusion Supplemental File" option if no changes are required to the previously-uploaded Home Infusion file with respect to the revised formulary (if applicable). See Exhibit 27.

<u>STEP 3B</u>

Select the "This Formulary requires changes to the Home Infusion Supplemental File" option if changes are required to the previously-uploaded Home Infusion file with respect to the revised formulary (if applicable). See Exhibit 27.

Note that you must upload your Home Infusion supplemental file using the HPMS Submit Home Infusion File option on the Formulary Submission Start page after your formulary is successfully validated and sent to desk review. If a supplemental file is not applicable for your formulary, skip to step 4.

Review CMS decisions for each record and click the "Accept" button. This will take you to the Formulary Resubmission – Confirm Submission page (see Exhibit 27).

The new version of the formulary will be validated again. You will receive an email confirmation when the formulary is successfully validated.

Note: While "Accepting" the review decisions results in the creation of a new version of the formulary to include only those changes that are deemed allowable, there is an exception to this process. If a protected class drug is added to the formulary during the submission window with unacceptable attributes, such as tiering or UM edits (PA, ST or QL), CMS will deny the record. By accepting the decisions through this line level process, the new formulary that is created will not contain the protected class drug. If the protected class drug is required on formularies with the current submission, then the formulary as a whole will be denied due to the drug's absence on the newly created file. This will result in Plan Finder suppression.

Note: You can view the contents of the new formulary on the Formulary Status History report by clicking the Full Formulary File option.

STEP 4B

Click the "Reject" button if you do not want a new version of the formulary to be created, applying only the approved changes. Rejecting the Line Level Decisions will automatically update the status of the formulary to denied.

Note: The "Reject" button is not displayed on the Plan Line Level Decision Accept/Reject page unless there is an approved version of the formulary.

CONFIRM SUBMISSION

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

On the **Formulary Resubmission - Confirm Submission** page (see Exhibit 28) review the information. Click the "OK" button to return to the Formulary Submission Start Page.

Exhibit 28 – Formulary Resubmission - Confirm Submission

Formulary Resubmission - Confirm Submission

Formulary Submission ✚

Formulary Name: Sample Formulary
Formulary ID: 00000032
Formulary Version:

Your formulary information was received. The formulary contacts listed below will receive an email that the formulary submission was received.

The HPMS will now perform a series of validation edits on the formulary submission. At the close of the validation process, a second email will be sent to the formulary contacts listed below. This email will either indicate a successful formulary upload or identify the errors detected during validation. If errors were detected, the formulary submission will be rejected. Once the errors are corrected, the formulary can be resubmitted.

Contacts notified of this formulary submission:

Contact Type	User Id	Name	Email
Upload User	tstusr	Test User	Test.User@hpmstest.com
Z0001	n/a	Test User2	Test.User2@hpmstest.com

OK

V. DELETE FORMULARY

The **Delete Formulary** page 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

Select **Delete Formulary** from the **Formulary Submission Start Page** (see Exhibit 4). 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 (see Exhibit 29) groups formularies in two sections:

Available for deletion - Formularies that are eligible for deletion.
Unavailable for deletion – Formularies that are approved by CMS, In Desk Review or uploaded but not processed are not eligible for deletion. After the plan-to-formulary crosswalk is locked, formularies associated with the plans are not available for deletion.

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

DELETE A FORMULARY

STEP 1
On the **Delete a Formulary Submission-Select a Formulary** page (Exhibit 29), select the formulary you wish to delete.

Exhibit 29 – Delete Formulary – Select a Formulary Page

STEP 2
Click the "Delete" button (Exhibit 29). This will take you to the Delete a Formulary Submission - Verify Deletion page.

VERIFY DELETION

The Verify Deletion page allows you to verify formulary information before you delete the formulary.

STEP 3
On the **Delete a Formulary Submission - Verify Deletion** page (Exhibit 30), review the page carefully and select the "Submit" button to finalize the deletion. This will take you to the Delete a Formulary Submission - Deletion Confirmation page.

Exhibit 30 – Delete Formulary – Verify Deletion page

Home » Formulary Submission » CY 20XX » Delete Formulary » *Verify Deletion*

Delete Formulary - Verify Deletion

Formulary Submission +

NOTE: Your data has not yet been submitted.

Formulary Name: Sample Formulary
Formulary ID: 00000052

Please carefully review the Formulary information before deleting this Formulary. Select the "Submit" button to delete your Formulary Information.

Contract(s) Covered by Formulary: Z0001

Contact(s) to be notified of this formulary deletion

Contact Type	User Id	Name	Email
Upload User	tstusr	Test User	Test.User@hpmstest.com
Z0001	n/a	Test User2	Test.User2@hpmstest.com

Therapeutic Category/Class Database Source Type: USP

Number of Cost Share Tiers: 4

Formulary includes drugs that need Prior Authorization? NO

Formulary includes drugs associated with a Step Therapy Management plan? NO

Back   Submit

DELETION CONFIRMATION

The **Submission Confirmation** page confirms successful deletion of your formulary. This page will also generate an email to all Formulary Contacts and the Formulary Upload Contact identified on this page, confirming successful deletion of the formulary.

<u>STEP 4</u>
On the **Delete a Formulary Submission - Deletion Confirmation** page (Exhibit 31), select the "OK" button to return to the Formulary Submission Start Page.

Note: You can also refer to the Formulary Status History report to verify successful deletion of the formulary.

Exhibit 31 – Delete Formulary – Delete Confirmation Page

Delete Formulary - Delete Confirmation

Formulary Submission ➕

Formulary Name: Sample Formulary
Formulary ID: 00000052

Your formulary information was successfully deleted. The formulary contacts listed below will receive an email confirming the successful deletion of this formulary.

Contacts notified of this formulary deletion

Contact Type	User Id	Name	Email
Upload User	tstusr	Test User	Test.User@hpmstest.com
Z0001	n/a	Test User2	Test.User2@hpmstest.com

OK

VI. SUBMIT FORMULARY TRANSITION POLICY/ATTESTATION

All organizations must attest and upload their Transition Policy as a part of their formulary submission. While the formulary submission is not dependent on Formulary Transition Policy submission in HPMS, you must successfully submit the Formulary Transition Policy before CMS will renew or approve your Part D contract. A Transition Policy status is successfully submitted when the following steps are completed:

- Authorization is attested.
- All attestation questions are answered "Yes". For Employer Organizations / Plan Types, all attestation questions are answered "Yes" except attestation #14.
- Implementation Statement is contained within the submitted transition policy.
- A transition policy is uploaded.

If you need to revise a previously-submitted Formulary Transition Policy, you should use the Revise Transition Policy Function (refer to Chapter VII).

STEP 1
Select **Transition Policy** from the **Formulary Submission Start** page (see Exhibit 4). This will take you to the Transition Submission Selection Contract page.

TRANSITION SUBMISSION - SELECT CONTRACT

STEP 2
On the **Transition Submission - Select Contract** page (see Exhibit 32), select one or more of the contracts listed on the page to associate with the Formulary Transition Policy and click the "Next" button. This will take you to the Transition Submission – Attestation Questions page. If you cannot see one of your contracts, please refer to Section I – Getting Started.

Exhibit 32 – Transition Submission - Contract Selection

Home » Formulary Submission » *CY 20XX* › *Transition Policy*

Transition Policy - Contract Selection

Formulary Submission   ✚

*Indicates required field

*Select one or more contracts

--Select All--
Z0001 - CONTRACT ONE
Z0002 - CONTRACT TWO
Z0003 - CONTRACT THREE
Z0004 - CONTRACT FOUR
Z0005 - CONTRACT FIVE
Z0006 - CONTRACT SIX
Z0007 - CONTRACT SEVEN
Z0008 - CONTRACT EIGHT

Back   Next

TRANSITION SUBMISSION – ATTESTATION QUESTIONS

STEP 3

On the **Transition Submission – Attestation Questions** page (see Exhibit 33), click the attestation authorization check box to indicate that you are authorized to submit the Attestation on behalf of your organization.

Exhibit 33 – Transition Submission - Attestation Questions

Home » Formulary Submission *CY 20XX* » Transition Policy » *Attestation Questions*

Transition Policy - Attestation Questions

Formulary Submission **+**

Contract(s) Selected: Z0001

NOTE: All attestation questions must be answered "Yes", with the exception of all Pace Organizations, Employer plans, and Employer only (800 series) can answer "No" to attestation #14.

*Indicates required field

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.**

IMPLEMENTATION STATEMENT

☐ *** An Implementation Statement is contained within the submitted transition policy that provides a detailed explanation of how Part D sponsors process transition requests within their adjudication system; how the pharmacy is notified when transition medication is processed at the point of sale; description of edits and explanation of the process pharmacies follow to resolve transition medication edits at the point of sale.**

	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 Number	**Question Text**	**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

STEP 4

Click the Implementation Statement check box to confirm that an implementation statement is included within the Transition Policy.

STEP 5

Select the appropriate answer for all the attestation questions and click "Next". This will take you to the Transition Policy Upload page.

Note: All attestation questions must be answered "Yes". All Pace Organizations, Employer plans of organization type 13 and 14 and Employer only S and H contracts (800 series) can answer "No" to attestation question # 14.

Upon successful completion of attestation questions, plans are required to upload a Formulary Transition Policy document as a Microsoft Word document (file extension .docx or .doc). The responses to the transition attestations will not be saved if the transition policy is not uploaded.

TRANSITION SUBMISSION - UPLOAD TRANSITION POLICY

STEP 6A

On the **Transition Submission - Upload Transition Policy** page (see Exhibit 34), you can select to upload a new Formulary Transition Policy from your local drive. Enter the full path and name of the Formulary Transition Policy document in the "Select a Transition Policy" field, e.g., c:\myformularyfile.doc(x). If you are unsure of the document name or location, click the "Browse" button to locate and attach the document. Note the Transition Policy name you enter, as this will be required for resubmission. Skip to Step 8.

Exhibit 34 – Transition Submission – Upload Transition Policy

STEP 6B

If you would like to use the same transition policy that you previously uploaded for another contract, click the "Select an Existing Policy" button. You will then be able to select the transition policy name from the drop-down list.

STEP 7

Click the "Next" button. This will take you to the Transition Submission – Verify Submission page.

TRANSITION POLICY-VERIFY SUBMISSION

STEP 8

On the **Transition Policy-Verify Submission** page (see Exhibit 35), verify the responses you provided and click the "Submit" button to submit your attestation. This will take you to the Transition Submission –Submission Confirmation page (see Exhibit 36).

Exhibit 35 – Transition Policy - Verify Submission

Home » Formulary Submission » *CY 20XX* Transition Policy » *Verify Transition Upload*

Transition Policy - Verify Submission

Formulary Submission +

Transition Policy Name: Sample Transition Policy
Transition Policy ID: 13
Transition Policy Version: 1

Alert: Please Note your transition policy data has not yet been submitted.

Contract(s) Selected: H0755

Question Number	Question Text	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.	Yes

TRANSITION SUBMISSION - CONFIRMATION

STEP 9

On the **Transition Submission - Confirmation** page (see Exhibit 36), a confirmation message will be displayed to notify the user that the Formulary Transition Policy and the attestation answers were successfully submitted. Click the "OK" button to go back to the Transition Submission – Select Contract page.

Exhibit 36 – Transition Policy Submission – Confirm Submission

Home » Formulary Submission » *CY 20XX* » Transition Policy » *Confirm Transition Upload*

Transition Policy - Confirm Submission

Formulary Submission +

Transition Policy Name: Sample Transition Policy
Transition Policy ID: 13
Transition Policy Version: 1

Contract(s) Selected: Z0001

Your Attestation and Transition Policy were successfully submitted.

Click on the OK button to return to the Select Contract Page

[OK]

VII. REVISE TRANSITION POLICY

The Revise Formulary Transition Policy functionality allows you to revise a Formulary Transition Policy that is already submitted. During the initial submission period, any Formulary Transition Policy with a status of "Submitted" can be revised. Once the initial submission period is closed, any Formulary Transition Policy with a status of Resubmission Requested can be revised.

STEP 1
Select **Revise Formulary Transition Policy** from the left navigation bar of the Formulary Submission Start page (See Exhibit 4). This will take you to the Transition Policy Resubmission – Select a Transition Policy page.

SELECT A TRANSITION POLICY

This page displays information on the submitted Transition Policies, such as the Formulary Transition Policy ID, Formulary Transition Policy Name, Formulary Transition Policy Status, and the Contracts Associated with the Transition Policy. There will be two tables displayed on this page. One table shows the formulary transition policies that are available for revision and the other table shows those policies that are not available for revision.

STEP 1
Select the Formulary Transition Policy ID and click the "Next" button (See Exhibit 37). This will take you to the Formulary Transition Policy Resubmission – Associate Contracts to Formulary Transition Policy page.

Note: When resubmitting, the word document (.doc or.docx) should contain track changes from your most recent transition policy submission and those changes must be limited to the reasons indicated in the resubmission request."

Note: If your Transition Policy is not available for revision and you need to resubmit, please send an email to partdtransition@cms.hhs.gov. In your email, please include the transition Policy ID, the associated contracts, and what modifications are needed to the transition policy.

Exhibit 37 – Revise Transition Policy - Select a Transition Policy

ASSOCIATE CONTRACTS TO TRANSITION POLICY

This page allows you to upload a revised transition policy. The page displays the contracts that were previously associated with the transition policy.

<u>STEP 1</u>
Enter the formulary transition policy name. Note the transition policy name you enter, as this will be required for resubmission.

Note: When resubmitting, the word document (.doc or .docx) should contain track changes from your most recent transition policy submission and those changes must be limited to the reasons indicated in the resubmission request.

<u>STEP 2</u>
Browse and select the revised formulary transition policy to upload.

Note: When resubmitting, the word document (.doc or .docx) should contain track changes from your most recent transition policy submission and those changes must be limited to the reasons indicated in the resubmission request.

Enter the full path and name of the Formulary Transition Policy word document in the "Select a Transition Policy" field, e.g., c:\myformularyfile.doc. If you are unsure of the document name or location, click the "Browse" button to locate and attach the document. You can only upload a Formulary Transition Policy as a Microsoft Word document. The acceptable file formats are .doc or .docx.

<u>STEP 3</u>
Indicate which of the attestation questions, implementation statement or if any other updates were made in the transition policy file to be re-submitted by selecting the respective check boxes. (See Exhibit 38.) You may also provide additional comments to describe the updates made on the transitional policy file to be uploaded.

STEP 4

Review the contract associations. If any contracts are no longer valid for this transition policy, you may unselect the check box next to the contract (see Exhibit 38).

STEP 5

Click the "Upload" button. This will take you to the **Revise Transition Policy –Confirmation** page (see Exhibit 39).

Exhibit 38 – Revise Transition Policy - Associate Contracts to Transition Policy

TRANSITION REVISION - CONFIRMATION

STEP 1

The **Revise Transition Policy – Confirmation** page (see Exhibit 39) displays the confirmation message that the formulary transition policy was successfully submitted. Click the "OK" button. This will take you to the **Transition Policy Resubmission Selection** page (see Exhibit 37).

Exhibit 39 – Transition Policy Resubmission Confirmation

Revise Transition Policy - Confirmation

Formulary Submission ✚

Transition Policy Name: Sample Policy
Transition Policy ID: 13
Transition Policy Version: 2

Contract(s) Selected: Z0001

Your revised Transition Policy was successfully submitted.

Click on the OK button to return to Revise Transition Policy start page.

[OK]

VIII. 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 Contract Association and Transition Policy Report
- Formulary Crosswalk Report
- Formulary Status History Report

STEP 1

As shown in Exhibit 40, on the HPMS Home page, select the Plan Formularies drop down from the HPMS top navigation bar. Then select the Formulary Reports menu item. This will take you to Formulary Reports Page.

Exhibit 40 – HPMS Home
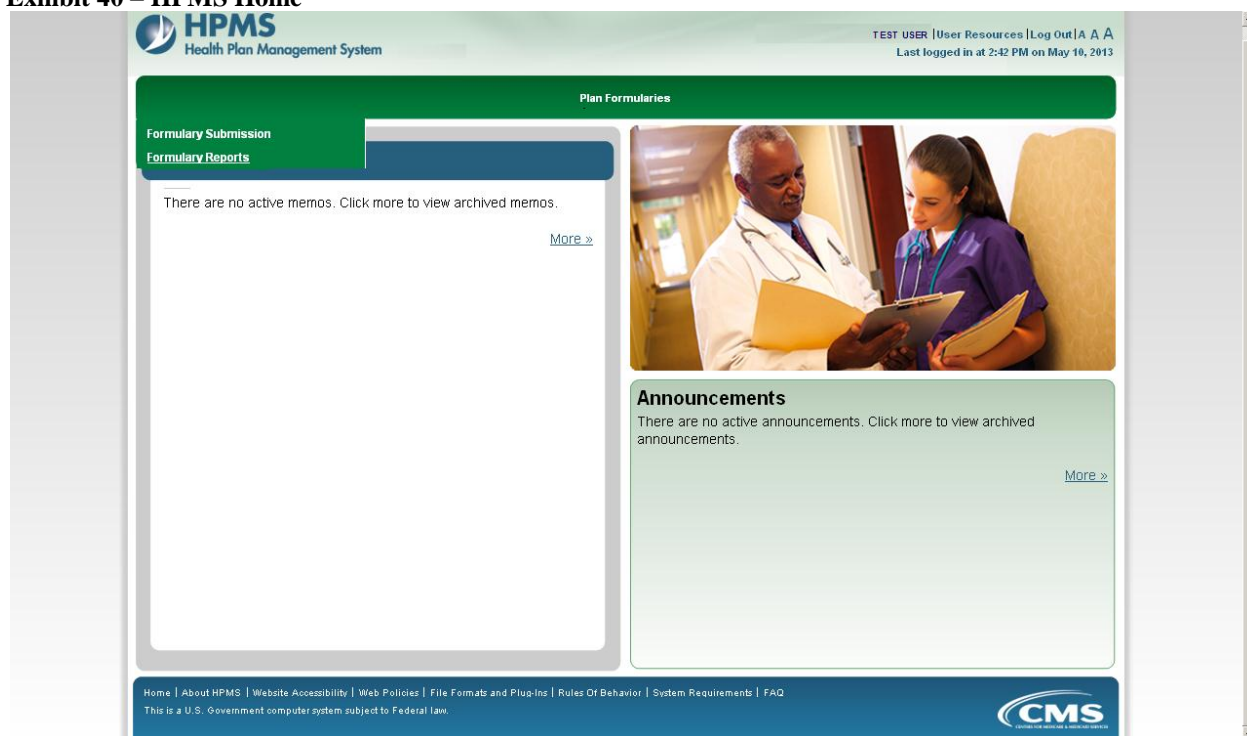
STEP 2

On the **Formulary Reports** page, select the appropriate contract year from the collapsible navigation menu, on the right side of the page. This takes you to the Report Selection page.

Exhibit 41 – Report Contract Year Selection

Home » Formulary Reports

Formulary Reports

The Formulary Reports module provides status history and change notification reports for all formulary submissions.

Formulary Reports

CY 2015
CY 2014
CY 2013
CY 2012
CY 2011
CY 2010
CY 2009
CY 2008
CY 2007
CY 2006

FORMULARY/BID CONTACT REPORT

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

<u>STEP 1</u>
On the **Report Selection** page (see Exhibit 42), select "Formulary/Bid Contact Report". This will take you to the Formulary Bid Report Contract Selection page.

Exhibit 42 – Formulary Report Selection

Home » Formulary Reports » CY 20XX

Report Selection

Formulary Reports +

NOTE: The Formulary Instructions for the reports are available within the Formulary Submission Module under Documentation.

*Indicates required field
*Select a Report:

Formulary/Bid Contact Report
Formulary Change Notification Report
Formulary Contract Year Comparison Report
Formulary Contract Association Report
Formulary Crosswalk Report
Formulary Status History Report
Change Notification Report - Partial Gap Coverage
Change Notification Report - Free First Fill
Change Notification Report - Home Infusion
Status History Report - Excluded Drug
Status History Report - Free First Fill
Status History Report - Partial Gap Coverage
Status History Report - Home Infusion

Back | Next

<u>STEP 2</u>
On the **Formulary/Bid Report - Contract Selection** page (see Exhibit 43), select the desired contract numbers and click the "Next" button. This will take you to the Formulary/Bid Contact Report (see Exhibit 44). A maximum of ten contracts may be selected.

IMPORTANT NOTE:
If the information from the Formulary/Bid Contact Report is incorrect, please update the Contract Level Contact Information in the HPMS Contract Management module. Plan level contact information should be updated in the HPMS Bid Submission module.

Exhibit 43 – Formulary Bid Report Contract Selection

Exhibit 44 – Formulary Bid Contact Report

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 any two different formularies.

<u>STEP 1</u>
On the **Formulary Reports – Select a Report** page (see Exhibit 42), select "Formulary Change Notification Report". This will take you to the Formulary Change Notification Report selection criteria page.

<u>STEP 2</u>
On the **Formulary Change Notification Report** selection criteria page (See Exhibit 45), select the desired Base Formulary ID and Version, as well as the Comparison Formulary ID and Version. (Versions will appear for selection after you select the Formulary ID and Comparison Formulary ID.) Click the "Next" button. This will take you to the Formulary Change Notification Report (see Exhibit 46).

Exhibit 45 – Formulary Change Notification Report Selection Criteria

Exhibit 46 – Formulary Change Notification Report

HPMS
Health Plan Management System

Formulary Change Notification Report

Search Criteria: This report was generated using the following search criteria.

Formulary IDs: 00000001 To 000000002
Compare: Version 1 To Version 1

The report compares detailed formulary data for the selected base formulary ID and the selected comparison formulary ID. The user may export the Formulary Differences section to a CSV file. In the Export Formulary Differences to CSV file, a cell will contain "NC" if the value did not change from the Base formulary.

FORMULARY COMPARISON

	Formulary ID-Version: 00000001-1	Formulary ID-Version: 00000002-1
Formulary Name	Formulary 1	Formulary 2
Review Status	*Resubmission Requested*	In Desk Review
Formulary Type	Update	Update
Contract(s)	Z0001 - Contract 1	Z0002 - Contract 2
Database Source	USP	USP
Number of Cost Share Tiers	4	4
Tier Label	Generic, Preferred Brand, Non-Preferred Brand, Specialty Tier	Generic, Preferred Brand, Non-Preferred Brand, Specialty Tier
Limited Access (Y/N)	Yes	Yes
Prior Authorization (0-3)	Prior Authorization Applies	Prior Authorization Applies
Prior Authorization File	Prior Authorization File[CSV]	Prior Authorization File[CSV]
Quantity Limit (Y/N)	Yes	Yes
Step Therapy (0-2)	Step Therapy Applies	Step Therapy Applies
Step Therapy File	Step Therapy File[CSV]	Step Therapy File[CSV]

Jump To: In Comparison Formulary
Jump To: Formulary Differences

In Base Formulary

Formulary ID: 00000001
Version: Version 1

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Amount	Unique Quantity Limit Days	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Step Therapy (0-2)	Number Of Step Therapy Groups
00000001	1	12345	TEST	TEST	TEST	3			0	Test ABC Agents	Test XYZ Class	0	

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

In Comparison Formulary

Formulary ID: 00000002
Version: Version 1

ALERT: No records found.

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

FORMULARY DIFFERENCES

Formulary IDs: 00000001 To 00000002
Compare: Version 1 To Version 1
NOTE: The values that highlight the differences shall be displayed in red text and cells with no differences will be blank.

Formulary ID	Version	RxCUI	Related BN	Related SCDC	Related DF	Cost Share Tier Level Value	Unique Quantity Limit Amount	Unique Quantity Limit Days	Prior Authorization (0-3)	Therapeutic Category	Therapeutic Class	Limited Access (Y/N)	Step Therapy (0-2)	Number Of Step Therapy Groups
00000001	1	12346	Test BN	Test SCDC 10 MG/ML	Test DF	2			0	Test Agents	Test Agents	0	0	
00000002	1	12346				3								

Export Formulary differences to File [CSV]

FORMULARY CONTRACT ASSOCIATION REPORT

The **Formulary Contract Association Report** provides a listing of which formularies are associated with a given Part D contract (if any).

STEP 1

On the **Formulary Reports – Select a Report** page (see Exhibit 42), select Formulary Contract Association Report. This will take you to the Formulary Contract Association Report selection criteria page.

STEP 2

On the **Formulary Contract Association Report** selection criteria page (see Exhibit 47), select the desired contract, and then click the "Next" button. This will take you to the **Formulary Contract Association Report** page.

Exhibit 47 – Formulary Contract Association Report Selection Criteria

Exhibit 48 – Formulary Contract Association Report

FORMULARY CROSSWALK REPORT

The **Formulary Crosswalk Report** identifies the formulary ID associated with each Part D plan and the status of the formulary. All formularies must be associated with at least one plan.

STEP 1

On the **Formulary Reports – Select a Report** page (see Exhibit 42), select "Formulary Crosswalk Report". This will take you to the Formulary Crosswalk Reports – Select a Contract page.

STEP 2

On the **Formulary Crosswalk Reports – Select a Contract** page (see Exhibit 49), select the desired contracts and then click the "Next" button. This will take you to the Formulary Crosswalk Report (see Exhibit 50).

Exhibit 49 – Formulary Crosswalk Report Select a Contract

Exhibit 50 – Formulary Crosswalk Report

FORMULARY STATUS HISTORY REPORT

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

STEP 1
On the **Formulary Reports – Select a Report** page (see Exhibit 42), select **Formulary Status History Report**. This will take you to the Formulary Status History Report selection criteria page.

STEP 2
On the **Formulary Status History Report selection criteria** page (see Exhibit 51), select the desired formularies, and then click the "Next" button. This will take you to the Formulary Status History Report.

Exhibit 51 – Formulary Status History Report Selection

STEP 3
On the Formulary Status History Report (see Exhibit 52), there are several actions you can take to view more details or get background information:

- To view the email sent regarding the formulary and PA/ST file upload, click the link provided under the formulary status link. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the email sent after PA/ST files are successfully uploaded from Revise PA/ST Criteria – Upload Page, click the link provided under the formulary Status column (see Exhibit 52) for the row where the PA/ST status is displayed in the "PA/ST Status Comments" column. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the text file previously submitted, click the "Submitted Text" hyperlink. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the full formulary file that includes the successfully validated changes as well as the existing formulary records, click the "Full Formulary File" hyperlink. A pop-up window will appear. This file is only available for versions of the formulary in successfully validated in desk review or Approved status. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the RxCUI report (see Exhibit 53) for the formulary click the "View" button. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the submitted PA/ST files, click the "View" button and then click the Submitted Prior Authorization File and Submitted Step Therapy File links (see Exhibit 53). A pop-up window will appear. This file only contains the latest submitted changes. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the approved formularies gate open/close history outside of the scheduled update windows, click the link "View Formulary Override Gate History Report" (see Exhibit 52). A pop-up window will appear. The following details will be displayed in the Formulary Override Gate History Report pop-up window: Formulary ID, Formulary Version, Gate Status (Open Gate/Close Gate), Gate Open/Close Date, Gate Auto-Close Date (see Exhibit 54). Note that the gate status of 'Open Gate' will be a hyperlink to the Email sent to users from Formulary Desk Review. When you have finished reviewing the information, click the "Close" button at the bottom of the window.
- To view the Full PA/ST files that include the successfully-validated changes as well as the existing criteria associated with the formulary, click the "View" button and then click the Full Prior Authorization File and Full Step Therapy File links (see Exhibit 53). A .CSV file opens, which lists all the Group Descriptions associated to the latest version of the formulary that is sent to desk review in excel format. When you have finished reviewing the information, close the .CSV file.
- To export the Formulary Status History Report to Excel, click the "Export to Excel" button.

Exhibit 52 – Formulary Status History Report

Formulary Status History Report

Formulary Reports ✚

View Formulary Override Gate History Report

Formulary ID	Formulary Version	Formulary Status	PA/ST Status and Comments	Version Deleted	Formulary Type	Submitted Text File	Full Formulary File	Report View	Last Approved Formulary Version	Last Approved Formulary Date	Most Recent Formulary Submission Date
00000002	2	Rejected By Validation	Resubmission Unrequested	No	Original	Submitted Text	N/A	View	1	05/07/2013	04/24/2013
00000002	2	Uploaded, but not Processed	N/A	No	Original	Submitted Text	N/A	View	1	05/07/2013	04/24/2013
00000002	1	Approved 05/07/2013	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	05/07/2013	04/24/2013
00000002	1	In Desk Review 05/07/2013	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	04/24/2013
00000002	1	In Desk Review	PA/ST Successfully Validated	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	04/24/2013
00000002	1	Successfully Validated 04/24/2013	N/A	No	Original	Submitted Text	Full Formulary File	View	N/A	N/A	04/24/2013
00000002	1	Rejected by Validation 04/24/2013	PA/ST Rejected By Validation	No	Original	Submitted Text	N/A	View	N/A	N/A	04/24/2013
00000002	1	Rejected by Validation 04/24/2013	N/A	No	Original	Submitted Text	N/A	View	N/A	N/A	04/24/2013
00000002	1	Uploaded, but not Processed 04/24/2013	N/A	No	Original	Submitted Text	N/A	View	N/A	N/A	04/24/2013

Back   Export to Excel

Exhibit 53 – Formulary Status History RxCUI Report

Exhibit 54 – Formulary Override Gate History Report

FORMULARY P&T COMMITTEE ATTESTATION REPORT

The **Formulary P&T Committee Attestation Report** provides attestation status for a given Contract(s).

STEP 1

On the **Formulary Reports – Select a Report page** (see Exhibit 55), select Formulary P&T Committee Attestation Report. This will take you to the Formulary P&T Committee Attestation Report selection criteria page.

Exhibit 55 – Formulary Report Selection

Home » Formulary Reports » *CY 20XX*

Report Selection   Formulary Reports   +

NOTE: The Formulary Instructions for the reports are available within the Formulary Submission Module under Documentation.

*Indicates required field
*Select a Report:

Change Notification Report - Partial Gap Coverage
Change Notification Report - Free First Fill
Change Notification Report - Home Infusion
Status History Report - Excluded Drug
Status History Report - Free First Fill
Status History Report - Partial Gap Coverage
Status History Report - Home Infusion
Status History Report - Over the Counter
Status History Report – Additional Demonstration Drug (ADD) File
Formulary PA/ST Attestation Report
Formulary P&T Committee Attestation Report
Formulary Transition Policy Report
Medicare-Medicaid Plan (MMP) - Submission Detail Report

Back   Next

STEP 2

On the **Formulary P&T Committee Attestation Report** selection criteria page (see Exhibit 56), select the desired contracts, and then click the "Next" button. This will take you to the Formulary P&T Committee Attestation Report page (See Exhibit 57).

Note that only contracts that have submitted P&T Committee attestations are displayed on the selection criteria page.

Exhibit 56 – P&T Committee Attestations – Select Contract Page

Home » Formulary Reports » *CY 20XX* » *Formulary Report Submission Parameter Page*

Formulary P&T Committee Attestation Report - Select   Formulary Reports   +
Parameters

Select One or More Contract Number(s):

Select All
Z0001 - CONTRACT ONE
Z0002 - CONTRACT TWO
Z0003 - CONTRACT THREE
Z0004 - CONTRACT FOUR

Back   Next

The **Formulary P&T Committee Attestation Report** displays the Contract, Plan Type, Formulary ID(s), Attestation Status and Answer # <#> (Yes or No or N/A) for the selected contracts.

- To export the **Formulary P&T Committee Attestation Report** to Excel, click the "Export to Excel" button.

Exhibit 57 – Formulary P&T Committee Attestation Report

Home » Formulary Reports »*CY 20XX* » *Formulary Attestation Report*

Formulary P&T Committee Attestation Report

Formulary Reports +

This report was generated using the following search criteria.
Contract Number(s):
- Z0001 - CONTRACT ONE
- Z0002 - CONTRACT TWO
- Z0003 - CONTRACT THREE
- Z0004 - CONTRACT FOUR

Contract	Plan Type	Formulary ID(s)	Attestation Status	Answer #1	Answer #2	Answer #3	Answer #4	Answer #5
Z0001	Sample Plan Type 1	00000001	Submitted	YES	N/A	NO	YES	YES
Z0002	Sample Plan Type 2	00000002	Submitted	YES	NO	YES	NO	YES
Z0003	Sample Plan Type 3	00000003	Submitted	NO	YES	YES	YES	YES
Z0004	Sample Plan Type 4	00000004	Not Submitted					

Back   Export to Excel

FORMULARY PA/ST ATTESTATION REPORT

The **Formulary PA/ST Attestation Report** provides attestation information for a given Contract(s).

STEP 1
On the **Formulary Reports – Select a Report** page (see Exhibit 55), select **Formulary PA/ST Attestation Report**. This will take you to the Formulary PA/ST Attestation Report selection criteria page.

STEP 2
On the **Formulary PA/ST Attestation Report** selection criteria page (see Exhibit 58), select the desired contracts, and then click the "Next" button. This will take you to the **Formulary PA/ST Attestation Report**.

Exhibit 58 – PA/ST Attestation – Select Contract Page

Home » Formulary Reports » CY 20XX » *Formulary Report Submission Parameter Page*

Formulary PA/ST Attestation Report - Select Parameters

Formulary Reports ➕

Select One or More Contract Number(s):

```
Select All
Z0001 - CONTRACT ONE
Z0002 - CONTRACT TWO
Z0003 - CONTRACT FOUR
Z0004 - CONTRACT FIVE
```

[Back] [Next]

STEP 3

The **Formulary PA/ST Attestation Report** displays the Contract, Plan Type, Formulary ID(s), Attestation Status and Answer # <#> (Yes or No) for the selected contracts.

- To export the **Formulary PA/ST Attestation Report** to Excel, click the "Export to Excel" button.

Exhibit 59 – Formulary PA/ST Attestation Report

Home » Formulary Reports » CY 20XX » *Formulary Attestation Report*

Formulary PA/ST Attestation Report

Formulary Reports ➕

This report was generated using the following search criteria.

Contract Number(s):
- Z0001 - CONTRACT ONE
- Z0002 - CONTRACT TWO
- Z0003 - CONTRACT FOUR
- Z0004 - CONTRACT FIVE

Contract	Plan Type	Formulary ID(s)	Attestation Status	Answer
Z0001	Sample Plan Type One	00000001	Submitted	YES
Z0002	Sample Plan Type Two	00000002	Not Submitted	
Z0003	Sample Plan Type Three	00000003	Not Applicable	NO
Z0004	Sample Plan Type Four	00000004	Submitted	NO

[Back] [Export to Excel]

FORMULARY TRANSITION POLICY REPORT

The **Formulary Transition Policy Report** provides detailed transition attestation and policy status for a given Contract.

STEP **1**

On the **Formulary Reports – Select a Report** page (see Exhibit 55), select **Formulary Transition Policy Report**. This will take you to the Formulary Transition Policy Report - selection criteria page.

STEP **2**

On the **Formulary Transition Policy Report selection criteria** page (see Exhibit 60), select the desired contracts, and then click the "Next" button. This will take you to the **Formulary Transition Policy Report**.

Exhibit 60 - Formulary Transition Policy Report - Select Parameters

STEP **3**

On the **Formulary Transition Policy Report** page (see Exhibit 61):
- Click the Transition Policy Status link for the contract to view the attestation questions and responses submitted. A pop-up window will appear (see Exhibit 62).
- To export the Attestation Questions and Reponses to Excel, click the "Export to Excel" button (see Exhibit 62). When you have finished viewing the information, click the "Close" button at the bottom of the pop-up window.

Note: The Transition Policy Status column displays 'NA' when there is no formulary associated with the contract.

Exhibit 61 - Formulary Transition Policy Report

Exhibit 62 - Transition Policy Status Popup

- Click the Transition Policy ID link for the contract to view the submitted policy document. A pop-up window will appear. When you have finished viewing the information, click the "Close" button at the bottom of the pop-up window.

IX. HOW TO SUBMIT SUPPLEMENTAL FILES

As part of the formulary submission process, you are required to submit certain supplemental files depending on what is included in your bid. Organizations must submit this supplemental information for all the plans offering this coverage. The supplemental files cannot be loaded until the organization has successfully submitted its related bids. This section provides detailed information on the how to submit the following supplemental files:

- Partial Gap Coverage (PGC)
- Free First Fill (FFF)
- Home Infusion (HI) Drug
- Over-the-Counter (OTC)
- Excluded Drug (ExD)

Only one supplemental file version may be submitted for each file type listed above per formulary. However, it is not required that all plans associated with a specific formulary offer supplemental coverage. For example, there may be four plans associated with a single formulary ID and only two of the plans offer partial gap coverage. As long as the plans that offer partial gap coverage will offer the exact same partial tier coverage (drug content and tiers) and are able to share the same partial gap coverage supplemental file, all four of these plans can be associated with the same formulary ID.

You begin the supplemental file upload process on the Formulary Submission Start page (Exhibit 4). If you need help accessing the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS Formulary Submission Module" in Chapter I.

The Submit Partial Gap Coverage File (PGC), Free First Fill (FFF) File, Home Infusion (HI) File, Excluded Drug (ExD) File and Over-the-Counter (OTC) File pages become available to you once your bid is written off to desk review.

- Partial Gap Coverage (PGC):
  Enhanced alternative (EA) plans (except MMPs) may offer additional gap coverage through a Part D supplemental benefit. This additional gap coverage would be above and beyond the standard benefit for generic and brand drugs and in addition to the Coverage Gap Discount Program for brand drugs. If your bid submission for an EA plan indicated that additional coverage is offered for a subset of drugs on a tier or tiers in the gap, then you must submit this partial tier gap coverage information via a supplemental Partial Gap Coverage file, before CMS will fully review the bid. Plans do not submit supplemental files for drugs that are on fully covered tiers. Partial Gap Coverage files must not include formulary drugs that are on fully covered tiers.
  Note: plans that will require distinct Partial Gap Coverage files based on the PBP submissions are not permitted to be associated with the same formulary ID.

- Free First Fill (FFF):
  Basic alternative or enhanced alternative (EA) plans may offer a free first fill benefit. If your bid submission indicated that a plan offers Free First Fill, you must submit the free first fill file before CMS will fully review the bid.

- Home Infusion (HI):
  If your bid submission indicated that a plan offers Part D Home Infusion drugs as a supplemental benefit under Part C, you must submit the home infusion file before CMS will fully review the bid.

- Excluded Drug (ExD):
  Enhanced alternative (EA) plans (except MMPs) may offer excluded drug coverage through a Part D supplemental benefit. If your bid submission for an EA plan indicated that excluded drug coverage is offered, then you must submit the excluded drug field before CMS will fully review the bid.

- Over-the-Counter (OTC):
  If your bid submission indicated that you offer OTC drugs, you must submit the OTC file before CMS will fully review the bid.

Note: While the following instructions demonstrate how to submit the Free First Fill file, you can also use these instructions to upload the Partial Gap Coverage, Home Infusion, Excluded Drug and OTC files. The steps taken to upload files are the same for each supplemental file type.

S<small>TEP</small> 1
As shown in Exhibit 4, select Submit Free First Fill File from the **Formulary Submission Start Page.** This takes you to the Free First Fill Supplemental Files-Select a Formulary page (see Exhibit 63).

S<small>TEP</small> 2
The **Free First Fill Supplemental File-Select a Formulary** page (see Exhibit 63) contains a table of all formularies that require a Free First Fill file. Note that only one formulary can be selected at a time. Select the formulary for which to upload a Free First Fill file and click "Next". This takes you to the Free First Fill Supplemental Files-Upload Supplemental File page.

Please note that only those plans with bid submissions that offer this benefit will be displayed. Plans that are linked to this formulary, but that do not offer this benefit will not be displayed as the supplemental file submission is not applicable to them.

Exhibit 63 – Submit Free First Fill File Select a Formulary Page

Home » Formulary Submission » CY 20XX » *Submit Free First Fill File*

Free First Fill Supplemental File - Select a Formulary

Formulary Submission ✚

This module is only available if your Bid has passed all validation checks and has been "Sent to Desk Review (DR)". You can check the current status of your Bid by reviewing the Bid Status History Report.

Formularies Requiring Free First Fill Upload

*Indicates required field.

			Submission Period - OPEN			
* Select Formulary	Formulary ID	Formulary Name	Formulary Version	Supplemental File Upload Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
○	00000002	FID Sample1	2	Successfully Validated	Z0001	
○	00000098	FID Sample2	5	Successfully Validated	Z0002	

Formularies Unavailable for Free First Fill Upload

		Submission Period - OPEN			
Formulary ID	Formulary Name	Formulary Version	Supplemental File Upload Status	Contract(s) Associated with Formulary	Contract(s) User is Unable to Access
00000080	FID Sample 3	1	Uploaded but not processed	Z0009, Z005	
00010008	FID Sample 4	8	Uploaded but not processed	Z0008	

Formularies Unavailable for Free First Fill Upload - All Plans are not Ready

		Submission Period - OPEN			
Formulary ID	Formulary Name	Formulary Version	Supplemental File Upload Status	Contract(s) Associated with Formulary	Supplemental Contract-Plan
00000100	FID Sample 5	9	Not Yet Uploaded	Z0009	Z0009-004
10010008	FID Sample 6	8	Not Yet Uploaded	Z0088	

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STEP 3

On the **Free First Fill Supplemental File– upload Supplemental File** page (see Exhibit 64), enter the name of the Free First Fill Supplemental file (.txt) you wish to upload. If you are unsure of the filename or location, click the "Browse" button to locate the file.

Select the "Upload" button to continue with the Free First Fill File submission process. This takes you to the Free First Fill Supplemental File-Verify Supplemental File Upload page.

Exhibit 64 – Free First Fill Supplemental File Upload Supplemental File

STEP 4

On the **Free First Fill Supplemental File-Verify Supplemental File Upload** page (see Exhibit 65), click the "Submit" button. This takes you to the Free First Fill Supplemental File-Submission Confirmation page.

Exhibit 65 – Free First Fill Supplemental File Verify Supplemental File

STEP 5

On the **Free First Fill Supplemental File-Submission Confirmation** page (Exhibit 66), review the information and click the "OK" button to complete the submission and return to the Free First Fill Supplemental File-Select a Formulary page.

The Submission Confirmation page provides a status of the successful upload. The system sends an email to the contact identified on this page.

After receiving the uploaded Free First Fill file, the HPMS performs a series of validation checks. At the close of the validation process, a second email is sent to the designated contact listed on this page. If errors were detected, the supplemental file submission is rejected. You must correct the Free First Fill file and resubmit the file using the Submit Free First Fill File function.

Exhibit 66 – Free First Fill Supplemental Files Submission Confirmation

X. 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. The following Supplemental File reports are available:

- Status History Reports:
    - Partial Gap Coverage
    - Free First Fill
    - Home Infusion
    - Excluded Drug
    - Over-the-Counter
- Change Notification Reports:
    - Partial Gap Coverage
    - Free First Fill
    - Home Infusion

SUPPLEMENTAL FILE STATUS HISTORY REPORTS

Note: While the following instructions demonstrate how to access and view the Status History Report – Free First Fill, you can also use these instructions for all of the Supplemental File Status History reports. The steps to access and view reports are the same for each report.

STEP 1
As shown in Exhibit 40, on the **HPMS Home** page, select the **Plan Formularies** drop down from the HPMS top navigation bar. Then select the Formulary Reports menu item. This will take you to Formulary Reports Page.

STEP 2
On the **Formulary Reports** page, select the appropriate contract year from the collapsible navigation menu, on the right side of the page. (See Exhibit 41). This takes you to the Report Selection page.

STEP 3
On the **Select a Report** page (see Exhibit 42), select Status History Report – Free First Fill. This takes you to the select by Contract or by Formulary ID Selection page.

STEP 4
On the **Select By Contract or By Formulary ID** page (Exhibit 67), you have three options to select the contracts or formularies to view:
- Click Select All Contracts or Select All Formularies
- Click a single contract or formulary ID
- Press the CTRL key and click multiple contracts or formularies
After selecting the appropriate contract or formulary IDs, click the "Next" button. This takes you to the Status History Report – Free First Fill Report page.

Exhibit 67 – Select By Contract or By Formulary ID Page

Home » Formulary Reports »*CY 20XX* » Supplemental Status History Report Parameter Page

Status History Report - Free First Fill - Select Parameters

Formulary Reports **+**

*Indicates required field

*Select By Contract or By Formulary ID:

By Contract ▾

*Select one or more contracts:

Select All Contracts
Z0001 - CONTRACT ONE
Z0002 - CONTRACT TWO
Z0003 - CONTRACT THREE
Z0004 - CONTRACT FOUR
Z0005 - CONTRACT FIVE

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STEP 5

On the Status History Report – Free First Fill page (Exhibit 68), you can review information about the supplemental file status, review the submitted text file, and view report details. You can also view formulary to plan ID details by clicking the **View Associated Plans** link.

Exhibit 68 – Status History Report – Free First Fill

Home » Formulary Reports » CY 20XX » Supplemental Status History Report Page

Status History Report - Free First Fill

Formulary Reports **+**

View Associated Plans

Formulary ID	Formulary Version	Associated Contracts	Supplemental File Status	Submitted Text File	Report View
00000001	4	Z0001	Rejected by Validation 3/6/2014 3:08:22 PM	Submitted Text	N/A
00000001	4	Z0001	Uploaded, but not Processed 3/6/2014 3:08:19 PM	Submitted Text	N/A
00000001	4	Z0001	Rejected by Validation 2/21/2014 10:46:41 AM	Submitted Text	N/A
00000001	4	Z0001	Plan chose to Use Previous File 2/21/2014 10:41:25 AM	N/A	N/A
00000001	3	Z0001	In Desk Review 2/21/2014 10:40:54 AM	Submitted Text	View report

Back   Export to Excel

STEP 5A – REVIEW INFORMATION ABOUT SUPPLEMENTAL FILE STATUS

In the Supplemental File Status column, you may have a Formulary ID assigned the status "Successfully Validated" or "Rejected by Validation". If this is the case, the status is displayed as a link. Click the hyperlink to view the email that was sent to you in a pop-up window (Exhibit 69). When you have finished reviewing the information, click the "Close" button at the bottom of the window.

Exhibit 69 – View Submission Email

STEP 5B – REVIEW THE SUBMITTED TEXT FILE

To view the text file previously submitted, click the Submitted Text link. A pop-up window appears (Exhibit 70). When you have finished reviewing the information, you may close the browser window for the Submitted Text.

Exhibit 70– Submitted Text File

STEP 5C – REVIEW REPORT DETAILS

In the "Report View" column, click the View Report hyperlink to view the drug detail page (Exhibit 71). A pop-up window appears. When you have finished reviewing the information, click the "Close" button at the top of the window. To Export the Free First Fill Report to Excel, click the "Export to Excel" button.

Exhibit 71 – Review Report Details

PARTIAL GAP COVERAGE, FREE FIRST FILL AND HOME INFUSION CHANGE NOTIFICATION REPORTS

Note: While the following instructions demonstrate how to access and view the Change Notification Report – Free First Fill, you can also use these instructions to access the Change Notification Report – Partial Gap Coverage and the Change Notification Report – Home Infusion reports. The steps taken to access and view reports are the same for each report.

STEP 1

As shown in Exhibit 40 on the **HPMS Home** page, select the **Plan Formularies** link in the left navigation bar. On the fly out menu, select the **Formulary Reports** link. This takes you to the Formulary Reports Contract Year Selection page.

STEP 2

On the **Formulary Reports Contract Year Selection** page (Exhibit 41), select the appropriate Contract Year link. This takes you to the Formulary Reports – Select a Report page.

STEP 3

On the **Select a Report** page (Exhibit 42), select "Change Notification Report – Free First Fill". This takes you to the Select By Contract or By Formulary ID Selection page.

STEP 4

On the **Select By Contract or By Formulary ID** page (Exhibit 72), select a contract ID or formulary ID you want to view in the report and click "Next". This takes you to the Submission Comparison Selection page.

Exhibit 72 – Free First Fill CNR Select By Contract or By Formulary ID Page

STEP 5

On the **Submission Comparison Selection page** (Exhibit 73), select two formulary versions to view in the report and click "Next". This takes you to the Change Notification Report – Free First Fill Report page (Exhibit 74).

Exhibit 73 – Submission Comparison Selection

Exhibit 74 – Change Notification Report – Free First Fill

XI. SUBMIT P&T (PHARMACY AND THERAPEUTIC) ATTESTATION

All organizations must attest their Pharmacy and Therapeutic (P&T) Committee Attestations as a part of their formulary submission. While the formulary submission is not dependent on Formulary P&T attestation in HPMS, you must successfully submit the P&T committee attestations before CMS will renew or approve your Part D contract. A P&T committee attestation is successfully submitted when all attestation questions are answered.

If you need to re-attest previously submitted attestations, send an email to CMS at partdtransition@cms.hhs.gov.

STEP 1
Select **P&T Committee Attestation** from the **Formulary Submission Start** page (Exhibit 4). This will take you to the P&T Committee Attestation – Select Contract page.

P&T COMMITTEE ATTESTATION – SELECT CONTRACT

STEP 2
On the **P&T Committee Attestation – Select Contract** page (Exhibit 75), select one or more of the contracts listed on the page and click the "Next" button. This will take you to the P&T Committee Attestation – Attestation Questions page. If you cannot see one of your contracts, please refer to Section I – Getting Started**.**

Exhibit 75 – P&T Committee Attestation – Select Contract

P & T Committee Attestation - Contract Selection

Formulary Submission ✚

*Indicates required field

*Select one or more contracts

```
--Select All--
Z0001 - CONTRACT ONE
Z0002 - CONTRACT TWO
Z0003 - CONTRACT THREE
Z0004 - CONTRACT FOUR
Z0005 - CONTRACT FIVE
Z0006 - CONTRACT SIX
```

Back   Next

P&T COMMITTEE ATTESTATION – ATTESTATION QUESTIONS

Exhibit 76 – P&T Committee Attestations – Attestation Questions

P & T Committee Attestation - Attestation Questions

Formulary Submission +

Contract(s) Selected: Z0001

*Indicates required field

As per 42 CFR 423.120(b)(1), a Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic (P&T) committee. Each sponsor must attest to the applicable attestations below in order for CMS to approve their contract.

Question Number	Question Text	* Answer
1	Sponsor is using the P&T Committee of its PBM for purposes of the Part D benefit.	○ Yes ○ No
2	If Sponsor answered yes to 1, Sponsor's PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Sponsor has no knowledge of the membership of the PBM's P&T Committee). Note: If answer is YES, the Sponsor must complete the P&T Committee Certification Statement. If you are changing PBMs and will be operating under a new confidential P&T committee, please submit the confidential P&T committee forms to cmsdrugbenefitimpl@cms.hhs.gov. The forms can be found in the 2015 Application for New and Expanding Medicare Prescription Drug Plans and Medicare advantage Prescription Drug Plans.	○ Yes ○ No ○ N/A
3	The majority of the membership of the Sponsor's P&T Committee used to develop and review the CY 2015 formulary submission are practicing physicians and/or practicing pharmacists (42 CFR 423.120(b)(1)(i)).	○ Yes ○ No
4	The membership of the Sponsor's P&T Committee used to develop and review the CY 2015 formulary submission includes at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Sponsor and pharmaceutical manufacturers (42 CFR 423.120(b)(1)(ii)).	○ Yes ○ No
5	The membership of the Sponsor's P&T Committee used to develop and review the CY 2015 formulary submission includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons (42 CFR 423.120(b)(1)(iii)).	○ Yes ○ No

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STEP 3

On the **P&T Committee Attestation – Attestation Questions** page (Exhibit 76), Select the appropriate answer for all the attestation questions and click "Next". This will take you to the P&T Committee Attestation Upload page.

Note: Attestation questions 1,3,4,5 can be answered 'Yes' or 'No'. You may choose to answer 'NA' for attestation question # 2.

P&T COMMITTEE ATTESTATION – VERIFY SUBMISSION

STEP 4

On the **P&T Attestation -Verify Submission** page (Exhibit 77), verify the responses you provided and click the "Submit" button to submit your attestation. This will take you to the P&T Attestation –Submission Confirmation page (Exhibit 78).

Exhibit 77 – P&T Committee Attestation – Verify Submission

Home » Formulary Submission » *CY 20XX* » P & T Committee Attestation » *P & T Attestation Verify*

P & T Committee Attestation - Verify Submission

Formulary Submission +

Alert: Please Note your data has not yet been submitted.

Contract(s) Selected: Z0001

Question Number	Question Text	Answer
1	Sponsor is using the P&T Committee of its PBM for purposes of the Part D benefit.	No
2	If Sponsor answered yes to 1, Sponsor's PBM is operating under a confidentiality agreement for purposes of the P&T Committee (meaning Sponsor has no knowledge of the membership of the PBM's P&T Committee). Note: If answer is YES, the Sponsor must complete the P&T Committee Certification Statement. If you are changing PBMs and will be operating under a new confidential P&T committee, please submit the confidential P&T committee forms to cmsdrugbenefitimpl@cms.hhs.gov. The forms can be found in the 2015 Application for New and Expanding Medicare Prescription Drug Plans and Medicare advantage Prescription Drug Plans.	N/A
3	The majority of the membership of the Sponsor's P&T Committee used to develop and review the CY 2015 formulary submission are practicing physicians and/or practicing pharmacists (42 CFR 423.120(b)(1)(i)).	Yes
4	The membership of the Sponsor's P&T Committee used to develop and review the CY 2015 formulary submission includes at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to the Sponsor and pharmaceutical manufacturers (42 CFR 423.120(b)(1)(ii)).	Yes
5	The membership of the Sponsor's P&T Committee used to develop and review the CY 2015 formulary submission includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons (42 CFR 423.120(b)(1)(iii)).	Yes

Back   Submit

P&T ATTESTATION – CONFIRMATION

<u>STEP 5</u>

On the **P&T Committee Attestation – Confirmation** page (Exhibit 78); a confirmation message will be displayed to notify the user that the attestation answers were successfully submitted.

Click the "OK" button to go back to the P&T Committee Attestation – Select Contract page.

Exhibit 78 – P&T Committee Attestation – Confirm Submission

Home » Formulary Submission » *CY 20XX* » P & T Committee Attestation » *P & T Attestation Confirm*

P & T Committee Attestation - Confirm Submission

Formulary Submission +

Contract(s) Selected: Z0001

Your Attestations were successfully submitted.

Click on the OK button to return to the Select Contract Page

OK

XII. SUBMIT PRIOR AUTHORIZATION / STEP THERAPY (PA/ST) ATTESTATION

All organizations must submit Prior Authorization / Step Therapy (PA/ST) Attestations as a part of their formulary submissions. While the formulary submission is not dependent on PA/ST Attestations in HPMS, you must successfully submit the PA/ST attestations before CMS will renew or approve your Part D contract. This is to ensure that Part D sponsors will comply with all CMS instructions to delete or change the PA or ST criteria in their formularies.

STEP 1

Select **PA/ST Attestation** from the **Formulary Submission Start** page (Exhibit 4). This will take you to the PA/ST Attestations – Select Contract page.

PA/ST ATTESTATION – SELECT CONTRACT

STEP 2

On the **PA/ST Attestation – Select Contract** page (Exhibit 79), select one or more of the contracts listed on the page and click the "Next" button. This will take you to the PA/ST Attestation – Attestation Questions page. If you cannot see one of your contracts, please refer to Section I – Getting Started.

Note: You can select more than one contract to attest or "Select All" to attest to all of your associated contracts.

Exhibit 79 – PA/ST Attestation – Select Contract

PA/ST COMMITTEE ATTESTATION – ATTESTATION QUESTIONS

Exhibit 80 – PA/ST Attestations – Attestation Questions

STEP 3

On the **PA/ST Attestation – Attestation Questions** page (Exhibit 80), select the appropriate answer for the attestation question and click "Next". This will take you to the PA/ST Verification page.

PA/ST ATTESTATION – VERIFY SUBMISSION

<u>STEP 4</u>

On the **PA/ST Attestation -Verify Submission** page (Exhibit 81), verify the response you provided and click the "Submit" button to submit your attestation. This will take you to the PA/ST Attestation –Submission Confirmation page (Exhibit 82).

Exhibit 81 – PA/ST Attestation – Verify Submission

Home » Formulary Submission » *CY 20XX* » PA/ST Attestation » *PA/ST Attestation Verify*

PA/ST Attestation - Verify Submission

Formulary Submission ✚

Alert: Please Note your data has not yet been submitted.

Contract(s) Selected: Z0001

Question Number	Question Text	Answer
1	Part D Sponsor/Applicant (organization) attests that it will comply with all Centers for Medicare & Medicaid Services' (CMS) instructions to delete or change the prior authorization (PA) and/or step therapy (ST) criteria for its CY 2015 formulary(ies). Where the organization's criteria disagree with CMS requirements, the organization attests it will provide clinical justifications for the PA and/or ST criteria in question. If the organization provides clinical justifications and agreement with CMS cannot be reached, the organization attests that it will comply with CMS requirements.	Yes

[Back]   [Submit]

PA/ST ATTESTATION – CONFIRMATION

<u>STEP 5</u>

On the **PA/ST Attestation – Confirmation** page (Exhibit 82), a confirmation message will be displayed to notify the user that the attestations were successfully submitted.
Click the "OK" button to go back to the PA/ST Attestation – Select Contract page.

Exhibit 82 – PA/ST Attestation – Confirm Submission

Home » Formulary Submission » *CY 20XX* » PA/ST Attestation » *PA/ST Attestation Confirm*

PA/ST Attestation - Confirm Submission

Formulary Submission ✚

Contract(s) Selected: Z0001

Your Attestations were successfully submitted.

Click on the OK button to return to the Select Contract Page

[OK]

XIII. SUBMIT MEDICARE-MEDICAID PLAN ADDITIONAL DEMONSTRATION DRUG FILE SUBMISSION

As part of the formulary submission process, Medicare-Medicaid Plan (MMP) applicants are required to submit a supplemental Additional Demonstration Drug (ADD) file. The ADD file cannot be loaded until the organization has successfully submitted its related bids and bids are written off to desk review. Only one ADD file may be submitted for each formulary. This section provides detailed information on the how to submit the ADD file.

You begin the **MMP Additional Demonstration Drug** file upload process on the **Formulary Submission Start page** (Exhibit 4). If you need help accessing the Formulary Submission Start Page, see the sub-section entitled "How to Access the HPMS Formulary Submission Module" in Chapter I.

STEP 1
As shown in Exhibit 4, select the **Submit MMP Additional Demonstration Drug File** link from the Formulary Submission Start Page**.** This takes you to the **MMP Additional Demonstration Drug File – Select a Formulary** page

MMP ADDITIONAL DEMONSTRATION DRUG FILE – SELECT FORMULARY

STEP 2
The **MMP Additional Demonstration Drug File-Select a Formulary** page (Exhibit 83) contains a table of all MMP formularies that are eligible for ADD file upload. Note that only one formulary can be selected at a time. Select the formulary for which you will upload an ADD file and click "Next". This takes you to the **MMP Additional Demonstration Drug File – Upload ADD File** page.

Exhibit 83 – MMP Additional Demonstration Drug File – Select Formulary

Home » Formulary Submission »*CY 20XX* » *Submit MMP Additional Demonstration Drug File*

MMP Additional Demonstration Drug File - Select a Formulary

Formulary Submission ➕

This module is only available if your Bid has passed all validation checks and has been "Sent to Desk Review (DR)". You can check the current status of your Bid by reviewing the Bid Status History Report.

Formularies Requiring ADD File Upload

*Indicates required field.

			Submission Period - OPEN		
* Select Formulary	Formulary ID	Formulary Name	Formulary Version	ADD File Upload Status	MMP Contract Associated with Formulary
⊙	00000001	Sample Formulary One	11	In Desk Review	Z0001
⊙	00000002	Sample Formulary Two	19	Rejected by Validation	Z0002

Back Next

MMP ADDITIONAL DEMONSTRATION DRUG FILE – UPLOAD FILE

STEP 3

On the **MMP Additional Demonstration Drug File – Upload File** page (see Exhibit 84), enter the name of the ADD file (.txt) you wish to upload. If you are unsure of the filename or location, click the "Browse" button to locate the file.

Exhibit 84 – MMP Additional Demonstration Drug File – Upload

Home » Formulary Submission »*CY 20XX* » *Submit MMP Additional Demonstration Drug File* » *ADD File Upload*

MMP Additional Demonstration Drug File - Upload

Formulary Submission ➕

Formulary Name: Sample Formulary One
Formulary ID: 00000001
Formulary Version: 11
Associated MMP Contract: Z0001

1. **Step 1.** Enter the name of the ADD file (.txt) you would like to upload. If you are unsure of the filename and/or location, click on the "Browse" button to locate the file.
2. **Step 2.** Click Upload.

*Indicates required field.

*Select ADD file for upload: [   ] Browse...

The ADD File will be applicable to the following plan(s):

Contract ID	Plan ID	Plan Name
Z0001	001	Sample Plan One

Back Upload

STEP 4

Click the "Upload" button to continue with the submission process. This takes you to the **MMP Additional Demonstration Drug File–Verify Upload** page.

MMP ADDITIONAL DEMONSTRATION DRUG FILE – VERIFY UPLOAD

<u>STEP 5</u>

On the **MMP Additional Demonstration Drug File-Verify Upload** page (Exhibit 85), review the information and click the "Submit" button. This takes you to the Additional Demonstration Drug File-Submission Confirmation page.

Exhibit 85 – MMP Additional Demonstration Drug File Upload Verification

Home » Formulary Submission » *CY 20XX* » Submit MMP Additional Demonstration Drug File » *Verify MMP Additional Demonstration Drug File*

MMP Additional Demonstration Drug File - Verify

Formulary Submission ✛

Formulary Name: Sample Formulary
Formulary ID: 00000001
Formulary Version: 11
Associated MMP Contract: Z0001

Please note that your data has not yet been submitted.

Please verify that your ADD file association is correct. Then click on the "Submit" button to complete your submission.

ADD File Associations:

Upload File: FR 1_YYYYY_Tier 5A.txt		
Contract ID	Plan ID	Plan Name
Z0001	001	Sample Plan One

Back   Submit

MMP ADDITIONAL DEMONSTRATION DRUG FILE – CONFIRM SUBMISSION

The MMP **Additional Demonstration Drug File – Submission Confirmation** page (Exhibit 86), provides a status of the successful upload. The system sends an email to the contact identified on this page.

After receiving the uploaded ADD file, the HPMS performs a series of validation checks. At the close of the validation process, a second email is sent to the designated contacts listed on this page. If errors were detected, the ADD file submission is rejected. You must correct the ADD file and resubmit the file using the Submit ADD file function.

Exhibit 86 – MMP Additional Demonstration Drug File – Confirm Submission

If you need to re-submit your ADD file, follow the same steps listed above. Previous submissions will be overwritten with the most recent file uploaded. To view the latest submitted file, you can view the "**Status History Report – Additional Demonstration Drug File**" under Formulary Reports.

XIV. MEDICARE-MEDICAID PLAN (MMP) – SUBMISSION DETAIL REPORT

The **Medicare-Medicaid Plan (MMP) – Submission Detail Report** displays the status (In Desk Review, Successfully Validated, Approved, Resubmission Requested and Not Submitted) of most recent submitted Additional Demonstration Drug File uploaded for the formulary. The report also lists MMP formularies for which ADD files are missing .The ADD files are considered missing if the status is "not submitted" or "rejected by validation" or "resubmission requested".

Note: This report is accessible to Medicare-Medicaid Plan users only.

STEP 1
As shown in Exhibit 40, on the HPMS Home page, select the **Plan Formularies** drop down from the HPMS top navigation bar. Then select the Formulary **Reports** menu item. This will take you to Formulary Reports Page (See Exhibit 41)

STEP 2
On the **Formulary Reports** page (Exhibit 41), select the appropriate Contract Year from the collapsible navigation menu, on the right side of the page. This takes you to the Report Selection page (Exhibit 42).

STEP 3
On the **Select a Report** page (Exhibit 42), select **Medicare-Medicaid Plan (MMP) – Submission Detail** Report.

Exhibit 87 – Medicare-Medicaid Plan (MMP) – Submission Detail Report

Home » Formulary Reports » CY 20XX » Medicare-Medicaid Plan (MMP) - Submission Detail Report

Medicare-Medicaid Plan (MMP) File - Submission Detail Report

Formulary Reports   **+**

Formulary ID	Contract	ADD File Status	ADD Upload Date	Formulary Drug Text File	Formulary Upload Date	OTC Text File	OTC Upload Date	State
00000001	Z0001	Not Submitted		Submitted Text	01/14/2014	N/A		Illinois
00000002	Z0002	In Desk Review	02/10/2014	Submitted Text	01/15/2014	N/A		California
00000003	Z0003	Rejected by Validation	02/11/2014	Submitted Text	02/21/2014	N/A		California
00000004	Z0004	Not Submitted		Submitted Text	01/17/2014	N/A		Illinois
00000005	Z0005	In Desk Review	02/24/2014	Submitted Text	01/21/2014	Submitted Text	02/23/2014	California

Back   Export to Excel

Submission File Layouts

On the **Medicare-Medicaid Plan (MMP) – Submission Detail Report** page (Exhibit 87), you can view the latest ADD-submitted text file. The report also displays the submitted formulary drug files and supplemental Over the Counter drug files associated with the formulary. The submission file layouts are available for download on clicking the submission file layouts hyperlink.

STEP 4
To view the most recent ADD file successfully submitted, click the "In Desk Review" link in the "ADD File Status" column. A pop-up window appears. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

Note: A Submitted text file is only available if its status is Successfully Validated or In Desk Review.

STEP 5
To view the formulary drug text file submitted for that formulary, click the "Submitted Text" link under the "Formulary Drug Text File" column. A window is displayed. When you have finished reviewing the information, "Close" the window.

STEP 6
To view the over the counter drug text file submitted for that formulary, click the "Submitted Text" link under the "Over The Counter Text File" column. A pop-up window appears. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

STEP 7
To view the submission file layouts, click the "Submission file layouts" hyperlink. A pop-up window appears. Click on the respective layouts to download formulary submission layout, supplemental over the counter drug text layout and MMP Additional Demonstration Drug file layout. When you have finished reviewing or downloading the information, click the "Close" button at the bottom of the window.

Exhibit 88 – Submission File Layouts

XV. STATUS HISTORY REPORT – ADDITIONAL DEMONSTRATION DRUG FILE

The **Additional Demonstration Drug File Status History Report** provides detailed status information about all versions of the ADD file for a given formulary ID.

STEP 1
On the **Formulary Reports – Select a Report** page (see Exhibit 42), select **Status History Report – Additional Demonstration Drug (ADD) File** report. This will take you to the ADD Status History report selection criteria page.

STEP 2
On the **Selection Criteria** page (Exhibit 89), you have three options to select the contracts or formularies to view:
- Click Select All Contracts or Select All Formularies
- Click a single contract or formulary ID
- Press the CTRL key and click multiple contracts or formularies

After selecting the appropriate contract or formulary IDs, click the "Next" button. This takes you to the Status History Report – ADD File Report page.

Exhibit 89 – Status History Report – ADD File Selection

STEP 3

On the Status History Report – ADD File page (Exhibit 90), you can review information about the ADD file status, review the submitted text file, and view report details. You can also view ADD file Gate Status History and PBP and ADD Justification history for all the contracts displayed on the ADD Status History report.

On the Status History Report – ADD File page (see Exhibit 90), there are several actions you can take to view more details or get background information:

- To view the email sent regarding the ADD file upload, click the link provided under the ADD file status column. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the text file previously submitted, click the "Submitted Text" hyperlink. A pop-up window will appear. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the ADD file gate history, click the link "View ADD File Gate Status History". A pop-up window will appear. The following details will be displayed in the ADD Gate History Report pop-up window: Formulary ID, Gate Status (Open Gate/Close Gate), Gate Open/Close Date, Gate Auto-Close Date. Note that the gate status of 'Open Gate' will be a hyperlink to the email sent to users from Bid Desk Review. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To view the PBP and ADD deficiencies report, click the link "View PBP and ADD Deficiencies Report". A pop-up window will appear. The following details will be displayed in the pop-up window: Formulary ID, Contract Plan Segment, PBP/ADD Deficiencies Email, PBP/ADD Deficiency File, and PBP/ADD Upload Date. The 'PBP/ADD Deficiency Email' column will have a hyperlink to the justification request email sent to users. The 'PBP/ADD Justification File' will have a hyperlink to the PBP/ADD Deficiencies file sent to the users when the deficiencies are communicated. When you have finished reviewing the information, click the "Close" button at the bottom of the window.

- To export the ADD Status History Report to Excel, click the "Export to Excel" button.

Exhibit 90 – Status History Report – ADD File

Home » Formulary Reports » CY 20XX » Supplemental Status History Report Page

Status History Report – Additional Demonstration Drug (ADD) File

Formulary Reports ✚

View ADD file Gate Status History Report

View PBP and ADD Deficiencies Report

Formulary ID	Formulary Version	Associated Contracts	ADD File Status	Submitted Text File	Report View
00000001	5	Z0001	In Desk Review 2/10/2014 3:30:56 PM	Submitted Text	N/A
00000001	5	Z0001	Uploaded, but not Processed 2/10/2014 3:30:54 PM	Submitted Text	N/A
00000001	5	Z0001	Rejected by Validation 2/10/2014 1:58:45 PM	Submitted Text	N/A
00000001	5	Z0001	Uploaded, but not Processed 2/10/2014 1:58:42 PM	Submitted Text	N/A

Back   Export to Excel

Exhibit 91 – View Submission Email

🖨 Print | Clos
Print Date: 7/11/201

HPMS
Health Plan Management System

Status History Report - ADD

FUT Email

Formulary ID:	00000001
Formulary Version:	1
Sent To:	Sample User
Email Address:	Sample.User@hpmstest.com
Subject:	Additional Demonstration Drug Supplemental File Validation Complete - 00000001-1
Date Sent:	05/23/2013
CC:	Sample.User1@hpmstest.com
Message:	

Sample User ,

Formulary ID: 00000001 Version: 1
Supplementary Data Type : Additional Demonstration Drug
Upload Date: 5/23/2013 3:44:46 PM
Contract Year: 2014
Processing Summary: Additional Demonstration Drug File Successfully processed.

The Additional Demonstration Drug supplemental file passed the validation process and will now be forwarded to CMS Desk Review.

For questions related to the content of this e-mail, please contact the HPMS Help Desk at 1-800-220-2028.

Thank you,

HPMS Web Staff

Close

Exhibit 92 – Submitted Text File
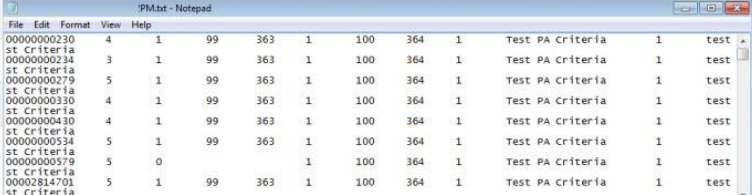
Home » Formulary Reports » *CY 20XX* » *Supplemental Status History Report Page*

Status History Report – Additional Demonstration Drug (ADD) File

Formulary Reports +

View ADD file Gate Status History Report

View PBP and ADD Deficiencies Report

Formulary ID	Formulary Version	Associated Contracts	ADD File Status	Submitted Text File	Report View
00000001	5	Z0001	In Desk Review 2/10/2014 3:30:56 PM	Submitted Text	N/A
00000001	5				
00000001	5				
00000001	5				

Back   Export to Excel

APPENDIX A: CY2015 FORMULARY AND SUPPLEMENTAL FILE LAYOUTS

Required File Format = ASCII File – Tab Delimited
Do not include a header record.
Filename extension is ".TXT"

During the initial formulary submission period (May 12 – June 2, 2014), the file must include all drugs in the formulary. After the initial formulary submission period, the file must include only changes.

For changes that take place after the initial submission period, plan sponsors are required to request that the gates be opened for future submission opportunities.

Table 1: CY 2015 Formulary File Record Layout

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
Change_Type	CHAR Always Required	3	Defines the type of change that is being made to the formulary. During the initial formulary submission period, all rows must be "ADD."	ADD = Add RxCUI to formulary DEL = Delete RxCUI from formulary UPD = Change fields in the existing RxCUI
RxCUI	NUMBER Always Required	Maximum 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
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

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
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
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 number that is accepted is "999".	60 (e.g., 9 tablets every 60 days) (e.g., 9 ml 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 D vs. Part B Step Therapy Only
Prior_Authorization_Group _Desc	CHAR Sometimes Required	100	Description of the drug's Prior Authorization group as it appears 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 Prior_Authorization_Type is 0 (No) or 3 (Part D. vs. Part B Authorization Only), then leave this field blank.	Antiemetics
Limited_Access_YN	CHAR Always Required	1	Is access to this drug limited to certain pharmacies?	0 = No 1 = Yes
Therapeutic_Category_Na me	CHAR Always Required	100	Enter the name of the category for the drug.	Analgesics

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
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?	0 = No Step Therapy Applies 1 = Step Therapy Applies 2 = Step Therapy Applies to New Starts 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 number that is 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.

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
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 Rx CUI, each Group Description must be unique. Note: For each Step Therapy Group Description, there must be an Rx CUI with a Step Therapy Value equal to 1.	Step_Therapy_Gr oup_Desc = "CHF Therapy" Step_Therapy_Gr oup_Desc = "Angina Therapy" Step_Therapy_Gr oup_Desc = "CVD Therapy"

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
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. Note: For each Step Therapy Group Description, there must be an Rx CUI with a Step Therapy Value equal to 1.	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)

Table 2: CY 2015 Free First Fill/Home Infusion File Record Layout

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

Table 3: CY 2015 Partial Gap Coverage File Record Layout

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. Note: The Partial Gap Coverage file must not include ALL of the drugs from the partially covered gap tier(s). In addition, drugs from fully covered tiers or tiers without additional gap coverage must not be submitted on the Partial Gap Coverage file.	210597

Table 4: CY 2015 Excluded Drug File Record Layout

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
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 are accepted is 5. i.e. "9.99999". The maximum number that is accepted is "9999.99".	9
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 is accepted is "999".	60 (e.g., 9 tablets every 60 days) (e.g., 9 mls every 60 days)
Capped_Benefit_YN	CHAR Always Required	1	Does the drug have a capped benefit limit?	0 = No 1 = Yes

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
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. **Note:** The Capped_Benefit_Quantity must be greater than the Quantity_Limit_Amount for a given NDC. If the Capped_Benefit_YN field is 0 = No, then leave this field blank. The maximum logical number that is accepted is "9999.99".	180
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 is accepted is "999".	365 (e.g., 180 tablets every 365 days)
Prior_Authorization_YN	CHAR Always Required	1	Is prior authorization required for the drug?	0 = No 1 = Yes
Prior_Authorization_Criteria	CHAR Sometimes Required	1500	The description of the drug's prior authorization criteria. If response to Prior_Authorization_YN = 0 (No), then leave this field blank.	
Step_Therapy_YN	CHAR Always Required	1	Does step therapy apply to this drug?	0 = No 1 = Yes

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Step_Therapy_Criteria	CHAR Sometimes Required	500	The description of step therapy protocol. If response to Step_Therapy_YN = 0 (No), then leave this field blank.	
Gap_Coverage_YN	NUM Always Required	1	Is this drug covered in the gap? Response should be 1 (Yes) regardless of whether this drug is on a tier that is fully or partially covered in the gap.	0 = No 1 = Yes

Table 5: CY 2015 Over The Counter File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NDC	CHAR Always Required	11	11-Digit National Drug Code	00258977120
UM_Type	CHAR Always Required	1	Indicate whether the NDC is included as part of general drug utilization management program (0) or a formal step therapy protocol (1) submitted for review and approval by CMS. The same NDC cannot be included in both a general drug utilization management program and a formal step therapy protocol.	0 = general UM program 1 = formal step therapy protocol
Step_Therapy_ Total_Groups	NUM Sometimes Required	2	Enter the total number of step therapy drug treatment groups or protocols in which the drug is included. If the response to UM_Type = 0 (No), then leave this field blank. The maximum logical number of groups is "25".	2
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.				

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Step_Therapy_ Group_Desc	CHAR Sometimes Required	100	Description of step therapy drug treatment groups or protocol. This step therapy group description must match a description found in your formulary text file. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Total_Groups. If the response to UM_Type = 0 (No), then leave this field blank. Note: For a given NDC each step therapy group description must be unique.	Step_Therapy_ Group_Desc = "Anti-Histamine Therapy"; Step_Therapy_ Group_Desc = "GERD Therapy"
Step_Therapy_ Step_Value	NUM Sometimes Required	1	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 the response to UM_Type = 0 (No), then leave this field blank. If the response to UM_Type = 1 (Yes), then the only allowable value is 1.	Step_Therapy_ Step_Value = 1 (e.g., Step 1 of 3); Step_Therapy_ Step_Value = 1 (e.g., Step 1 of 2)

Table 6: CY 2015 Medicare-Medicaid Plan (MMP) Additional Demonstrational Drug (ADD) File Layout

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
MMP_NDC	CHAR Always Required	11	11-Digit National Drug Code. When no NDC is available enter the applicable Uniform Product Code (UPC) or Health Related Item Code (HRI). Do not include any spaces, hyphens or other special characters.	00012533460

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
MMP_Tier	CHAR Always Required	1	The cost share tier level associated with the drug (assumes that the drug is assigned to only one tier value). Tier values 1-6 are consistent with the selection of tier level options available to data entry users in the Plan Benefit Package software. Tier values of 1 or 2 can only be selected for 2-tier formulary designs.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6
MMP_QL_YN	CHAR Always Required	1	Does the drug have a quantity limit (MMP_QL_YN) restriction?	0 = No Quantity Limits 1 = Quantity Limits Apply
MMP_QL_Amt	NUM Sometimes Required	7	If the MMP_QL_YN is" 1" (meaning limits apply), enter the **quantity limit amount** (MMP_QL_Amt) for a given prescription or time period (typically 1 month). The units for this amount must be defined by a unit of measure e.g., number of tablets, milliliters, grams, etc. The maximum logical number that will be accepted is "9999.99". If the MMP_QL_YN field is "0" (No), then leave this field blank.	9 (e.g., 9 tablets)
MMP_QL_Days	NUM Sometimes Required	3	The **number of days** (MMP_QL_Days) associated with the quantity limit amount. The maximum logical number that will be accepted is "365". If the MMP_QL_YN field is "0" (No), then leave this field blank.	30 (e.g., 9 tablets every 30 days)

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
MMP_CapBen_YN	CHAR Always Required	1	Does the drug have a **capped benefit** (MMP_CapBen_YN) limit?	0 = No 1 = Yes
MMP_CapBen_Amt	NUM Sometimes Required	7	If the MMP_CapBen_YN field is "1" (meaning limits apply), enter the **capped benefit limit amount** (MMP_CapBen_Amt) for a given prescription or time period. Plans may elect to have a capped benefit amount without a quantity limit. However if a quantity limit applies as well, the capped benefit amount must be greater than the quantity limit amount. The units for this amount must be defined by a unit measure e.g., number of tablets, number of milliliters, number of grams, etc. The maximum logical number that will be accepted is "9999.99". The capped benefit amount **must** be greater than the quantity limit amount. If the MMP_CapBen_YN field is "0" (No), then leave this field blank.	180 (e.g., 180 tablets)
MMP_CapBen_Days	NUM Sometimes Required	3	The **number of days** (MMP_CapBen_Days) associated with the capped benefit limit. The capped benefit days **must** be greater than the quantity limit days. The maximum logical number that will be accepted is "365". If the MMP_CapBen_YN field is "0" (No), then leave this field blank.	365 (e.g., 180 tablets every 365 days)

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
MMP_PA_YN	CHAR Always Required	1	Is **prior authorization** (MMP_PA_YN) required for the drug?	0 = No 1 = Yes
MMP_PA_Criteria	CHAR Sometimes Required	3000	The description of the **prior authorization criteria** (MMP_PA_criteria) for this drug. If the MMP_PA_YN field is "0" (No), then leave this field blank.	
MMP_ST_YN	CHAR Always Required	1	Does **step therapy** (MMP_ST_YN) apply to this drug?	0 = No 1 = Yes
MMP_ST_Criteria	CHAR Sometimes Required	1000	The description of the **step therapy protocol** (MMP_ST_Criteria) for this drug. If the MMP_ST_YN field is "0" (No) then leave this field blank.	

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

APPENDIX B: FORMULARY UPLOAD FILE INSTRUCTIONS

Note: To download all upload file formats, click the **Submission File Layouts** link in the Documentation section of the Formulary Submission Start Page.

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 plans. The Appendix A: Formulary file Record Layout is provided for your reference. Please note that only proxy RxCUI provided in the CY 2015 Formulary Reference File may be 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 "Required," "Optional," or "Conditional." The conditional fields should be populated if the condition is met as outlined below. When an optional or conditional field is left blank, the blank must be represented by a tab delimiter.

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 – Change_Type:
The formulary file layout has been amended to include a change type field.
REQUIRED: During the initial submission period, the value should be "ADD" for all records. During review period, only changes to the formulary file will be submitted. Each RxCUI submitted will need a change type field value of "ADD", "DEL", or "UPD". The HPMS system will perform a validation on RxCUIs that have the update flag to ensure that a change was made.

Field 2 – RxCUI:
REQUIRED: Each record should include up to 8-digit numeric RxCUI associated with the formulary. The list of acceptable RxCUI can be found in the CY 2015 Formulary Reference RxCUI File. RxCUI should only be entered once in this formulary file.

Field 3 – Tier_Level:
REQUIRED: Enter the cost share tier level value associated with the drug. Include a value from 1 to 6 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. For MMPs, the only allowable values are 1 and 2.
Field 4 – 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 5 – 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 6 - 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 7 - 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 8 – 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.

Field 9 – Prior_Authorization_Group_Desc:
CONDITIONAL: If Prior Authorization 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 10 – 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 11 – **Therapeutic_Category_Name**:
REQUIRED: Enter the name of the category for this drug.

Field 12 – **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 13 – **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.

- 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.

- If RxCUI is equal to the 0003686 (OTC CUI), then the Step_Therapy_Type fields must be equal to 1 or 2.

Field 14 – **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 15 – **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 16 – **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 Field15. 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

NOTE: If RxCUI is equal to the 0003686 (OTC CUI), then the Step_Therapy_Step_Value must always equal 1.

PRIOR AUTHORIZATION FILE INSTRUCTIONS

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, it must be represented by a tab delimiter.

For a given PA Group Description, a "1" must be entered for the **PA_Criteria_Change_Indicator** field if the criteria are different than the values on the CY 2014 formulary version approved as of February 1, 2014. In addition, if PA is required for drugs that are on your CY2015 formulary that were either 1) not on the approved CY 2014 file, OR 2) did not previously require a PA for CY 2014, then a "1" must be entered. If the criteria are completely unchanged, a "0" must be entered.

Please Note: For those plans that have PA Type 3 only, you are not required to upload a blank PA file. You will still indicate on the formulary questions page that the formulary includes Type 3 PA, but there will be a check box on the formulary upload page that allows you to complete your formulary submission without uploading a PA file. The PA criteria document must be a tab delimited text file and a filename extension of ".txt". Do not include a header record.

The PA_Change_Type value is a new field for the Prior Authorization File Record Layout.

Required File Format = ASCII File - Tab Delimited
Do not include a header record

Filename extension should be ".TXT"

Table 7: Prior Authorization File Instructions

Field Name	Field Type	Maximum Field Length	Field Description
PA_Change_Type	CHAR Always Required	3	Defines the type of change that is being made to the Prior Authorization File. During the initial formulary submission period, all rows must be "ADD." ADD = Add Group Description to file UPD = Change fields for an existing Group Description
Prior_Authorization_Group_Desc	CHAR Always Required	100	Description of the Prior Authorization group as it 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 2014, 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 drugs 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 Step Therapy, 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., co morbid 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 drugs.
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 attributes necessary for PA to be considered, e.g., specialist in a field or registered under a certain program.

Field Name	Field Type	Maximum Field Length	Field Description
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.

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 (<), and 3) semi-colon (;).

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.

The ST_Change_Type value is a new field for the Step Therapy File Record Layout.

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

Table 8: Step Therapy File Instructions

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
ST_Change_Type	CHAR Always Required	3	Defines the type of change that is being made to the Step Therapy File. During the initial formulary submission period, all rows must be "ADD."	ADD = Add Group Description to file UPD = Change fields for an existing Group Description

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 an 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.	
ST_Criteria_Change_Indicator	CHAR Always Required	1	If the ST criteria content did not change for this group description compared to CY 2014, please place a "0" in this field. If this group description is new, or the criteria content changed in any way, please place a "1" in this 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 (<), and 3) semi-colon (;).

APPENDIX C: FORMULARY UPLOAD AND SUPPLEMENTAL FILES EDIT RULES - CY 2015

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 includes the 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 might take place:
a) On-line Upload
b) Formulary Validation Process

ON-LINE UPLOAD

The user CANNOT continue with the upload if any of the following edit checks fail:
1. The system searches for **HPMS restricted characters** (greater than >, less than < and, semi-colon ;) in the upload file and **rejects** submissions if the file contains one or more restricted characters.

FORMULARY VALIDATION PROCESS

An email is sent to the person who uploaded the formulary, as well as the formulary contact for each contract associated with the formulary. This email notifies the user if the edit checks are successful and otherwise contain an error message for each edit check that did not pass. The edit checks are as follows:

An email is sent to the person who uploaded the formulary, as well as the formulary contact for each contract associated with the formulary. This email notifies the user if the edit checks are 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 **Change_Type, 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 populated for submission.
3. **Change_Type** value must be ADD, UPD or DEL; the value cannot be null. Change_Type must be ADD in the initial submission.
4. While revising the formulary:
   a. Change_Type must be ADD if the drug is not contained in the latest version of the formulary that is in desk review which is not denied or withdrawn.

b. Change_Type must be UPD if the drug is contained in the latest version of the formulary that is in desk review which is not denied or withdrawn and there is a change in the characteristics of the drug.

c. Change_Type should be DEL if the drug is contained in the latest version of the formulary that is in desk review which is not denied or withdrawn and you want to delete the drug from the revised version.

d. If the Change_Type is UPD at least one value must be different from the current version of the formulary that is in desk review which is not denied or withdrawn

5. The formulary file's RxCUIs are compared against the RxCUI in the Formulary Reference File to determine the validity of the RxCUIs in the formulary file.

6. Each **RxCUI** must be unique in the submission file.

7. For **non-MMP** formularies, the maximum value for the **Tier_Level** field in the formulary file must be equal to the number of cost share tiers entered during HPMS data entry.

8. For **non-MMP** formularies, the value of the **Tier_Level** field must be 1 to 6.

9. **Non-MMP** formulary submission files must contain at least one row for every tier (other than the Excluded Drug only tier) identified on the **Formulary Tier Information** page.

10. **Non-MMP** formulary submission files must NOT contain any rows with a **Tier_Level** field value equal to the tier number defined as the **Excluded Drugs Only** tier on the Formulary Tier Information page.

11. **MMP Formulary** submission file must contain at least one row for each tier defined as **Medicare Tier (**Generic Drugs, Brand Drugs, Preferred Brand Drugs, Non-Preferred Brand Drugs, $0 Drugs, Preferred Generic Drugs, and Non-Preferred Generic Drugs).

12. **MMP Formulary** submission files must NOT contain any rows with the **Tier_Level** field value equal to tier numbers defined as **Non-Medicare tiers**. Note: The tier model selected on the **Formulary Tier Information** page may include placeholder tiers for non-Part D drugs that are not included on the formulary file.

13. The **Drug_Type_Label** must have a value of **1 to 6**; it cannot be null.

14. 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.

15. 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.

16. The value of **Limited_Access_YN** field must be 0 or 1.

17. If the **Quantity_Limit_YN** is **1 = Quantity Limits Apply**, then the **Quantity_Limit_Amount** field must be a 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.

18. If the **Quantity_Limit_YN** is **1** = **Quantity Limits Apply**, the **Quantity_Limit_Days** field must be numeric and must be a value of 1 - 999.

19. If the **Quantity_Limit_YN** is **0 = NO Quantity Limits**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be null.

20. The **Prior_Authorization_Type** field must be a value of 0 to 3.

21. 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.

22. 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** applies for the **Prior_Authorization_Type** field in the formulary file.
23. If the **Prior_Authorization_Type** field is **greater than 0,** then the **Prior_Authorization_Group_Desc** must be populated.
24. If the **Prior_Authorization_Type** field is equal to 0, then the **Prior_Authorization_Group_Desc** must be null.
25. 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.
26. The **PA Group Description** must match the current version (latest version in desk review that is not denied or withdrawn) when the **PA Type is > 0.**
27. 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.
28. 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.
29. 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.
30. 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.
31. If the **Step_Therapy_Type** is **greater than 0**, then the **Step_Therapy_Total_Groups, Step_Therapy_Group_Desc** and **Step_Therapy_Step_Value** fields must be populated.
32. If the **Step_Therapy_Type** is equal to **0**, then the **Step_Therapy_Total_Groups** field must be null.
33. The **Step_Therapy_Type** field must be a value of 0 to 2.
34. If the **Step_Therapy_Total_Groups** field is populated, it must be numeric, greater than 0 and less than 100 (1 to 99; whole numbers only).
35. If the **Step_Therapy_Step_Value** field is populated, it must be numeric, greater than 0 and less than 100 (1 to 99; whole numbers only).
36. If **Step_Therapy_Total_Groups** is populated, 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**.
37. If **Step_Therapy_Total_Groups** is null, then **Step_Therapy_Group_Desc and Step_Therapy_Step_Value** fields must be null.
38. If **Step_Therapy_Total_Groups** is populated, then **Step_Therapy_Step_Value and Step_Therapy_Group_Desc**, fields must be populated.
39. For each **RxCUI**, the same **Step_Therapy_Group_Desc** must not occur more than once in the step therapy trailer.
40. 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.
41. If the **Step_Therapy_Group_Desc** field is populated, ensure that the **Step_Therapy_Group_Desc** field is not greater than 100 characters in length.

42. The **maximum number** of errors that are allowed before processing of the formulary file stops is **200**.
43. The **Formulary and dependent files** (Prior Authorization and/or Step Therapy files), if submitted, are **rejected** if the validation does not meet these rules.
44. If all contracts associated with the formulary are **bid approved**, the system validates that a drug may **Not** be moved from a tier that is **fully** or **partially** covered in the gap to a tier that has **No** gap coverage in the PBP.
45. The system automatically removes leading and trailing asterisks **(*)** from the **Therapeutic_Category_Name** field.
46. The system automatically removes leading and trailing asterisks **(*)** from the **Therapeutic_Class_Name** field

Prior Authorization File:
1. The file must be in a **tab-delimited text** (.txt) format and must not contain a **header record.**
2. 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 are rejected if the validation does not pass.
3. For the Prior Authorization File, the system ensures that the **Change_Type, Prior_Authorization_Group_Desc, PA_Criteria_Change_Indicator, Covered_Uses,** and **Coverage_Duration** fields are not null.
4. **Change_Type** value must be ADD or UPD; the value cannot be null. Change_Type must be ADD in the initial submission.
5. The system searches for **HPMS restricted characters** (greater than >, less than < and semi-colon) in the upload file and rejects submissions if the file contains one or more restricted characters.
6. The system ensures that there is an open edit request for the Group Description with **UPD Change_Type.**
7. The system ensures that at least one field value is different from the current version (most recent version in desk review that is not denied or withdrawn) for the Group Description with an **UPD Change_Type.**

Note: The system automatically deletes the Group Descriptions from the Prior Authorization file when they are deleted from the Formulary File.

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 validates that the **Change_Type, Step_Therapy_Group_Desc** and the **Step_Therapy_Criteria** fields are populated.
4. **Change_Type** value must be ADD or UPD; the value cannot be null. Change_Type must be ADD in the initial submission.

5. The system searches for **HPMS restricted characters** (greater than >, less than < and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.
6. The system ensures that there is an open edit request for the Group Description with **UPD Change_Type.**
7. The system ensures that at least one field value is different from the current version (most recent version in desk review that is not denied or withdrawn) for the Group Description with an **UPD Change_Type.**

Note: The system automatically deletes the Group Descriptions from the Step Therapy file when they are deleted from the Formulary File.

SUPPLEMENTAL AND ADD FILE VALIDATIONS

Partial Gap Coverage/Free First Fill/Home Infusion:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
2. The **Partial Gap Coverage, Home Infusion and Free First Fill** submissions must contain an RxCUI that exists in the formulary submission file.
3. Supplemental files can only be submitted if **at least one plan** associated with the current version of the formulary has a validated bid submission.
4. Each **RxCUI** must be **unique** in the submitted file.
5. All RxCUIs included in the file must apply to all plans associated with the file. Plans that require different versions of a particular file based on the number of RxCUIs or the specific drugs covered cannot share the same supplemental file and therefore cannot be linked to the same formulary ID.
6. **Strip leading zeroes** from the **RxCUI field** in the PGC, FFF, and HI submission files.
7. The system creates a flag to indicate if the current **PGC, FFF, or HI** submission is identical to the previous successfully submitted file.
8. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and will reject submissions if the file contains one or more restricted characters.
9. At least one plan associated with the formulary must have a **PBP tier** designation of partial gap coverage for each RxCUI in the partial gap coverage supplemental file.
10. The partial gap coverage file must not include **all** of the RxCUIs that are on a formulary tier indicated as being only partially covered in the gap.
11. The partial gap coverage file must not include **any** of the RXCUIs that are on fully covered formulary tiers in the coverage gap or on tiers with no additional gap coverage.
12. If all contracts associated with the formulary are **bid approved**, the system validates that any RxCUIs that are moved from **full gap** tier to **partial gap** tier must be included in the **Partial Gap Coverage** file.
13. If all contracts associated with the formulary are **bid approved**, the system validates an **RxCUI may not be removed from the Partial Gap Coverage (PGC)** file, unless it is also removed from the revised formulary or the RxCUI is moved from a partially covered tier to a fully covered tier. Any drug removed from the formulary or moved to a fully covered tier must be removed from the PGC file. RxCUIs will not be allowed to move from a partially covered tier to a tier with no additional gap coverage.
14. If all contracts associated with the formulary are **bid approved**, the system validates that an **RxCUI may not be removed from the FFF and HI file,** unless it is also removed from the revised formulary.
15. Until all the contracts associated with the formulary are bid approved, the system will send a reminder to add HI eligible drugs to the HI file when HI eligible drugs are added to the formulary and are not added to HI file.
16. If all contracts associated with the formulary are bid approved, the system validates that an **RXCUI may be added to the HI file if the drug is HI eligible** and is **not on the last approved version of the formulary**.

Excluded Drug:

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.
2. The system validates the **lengths and values** for all fields (see file layout).
3. The Tier field must be a number between **1 and 6**.
4. Each **NDC** must be **unique** in the submitted file, **populated**, and **11 characters in length.**
5. All NDCs included in the file must apply to all plans associated with the file. Plans that require different versions of a particular file based on the number of NDCs or the specific drugs covered cannot share the same Excluded Drug supplemental file and therefore cannot be linked to the same formulary ID.
6. 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, and Gap_Coverage_YN.**
7. For the **Excluded Drug** file, **if 0 = No** is entered for **Quantity_Limits_YN**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be null.
8. For the **Excluded Drug File, if 1 = YES** is entered for **Quantity_Limits_YN**, then the **Quantity_Limit_Amount** and **Quantity_Limit_Days** fields must be populated.
9. If the value is 1 for the **Quantity_Limits_YN** field, then the **Quantity_Limit_Amount** field must contain a numeric value of 1 thru 9999.99.
10. If the value is 1 for the **Quantity_Limits_YN** field, then the **Quantity_Limit_Days** field must contain a numeric value of 1 thru 999.
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 **Capped_Benefit_YN**, then **Capped_Benefit_Quantity** and **Capped_Benefit_Days** must be populated.
13. If the value is 1 for the **Capped_Benefit_YN** field, then the **Capped_Benefit_Quantity** field must contain a numeric value of 1 thru 9999.99.
14. If the value is 1 for the **Capped_Benefit_YN** field, then the **Capped_Benefit_Days** field must contain a numeric value of 1 thru 999.
15. For the **Excluded Drug file, the Capped_Benefit_Quantity** must **be greater than th**e **Quantity_Limit_Amount** for a given NDC if both Capped_Benefit_Quantity and Quantity_Limit_Amount are non-blank.
16. The **CapBen_Days** field must be greater than the **QL_Days** field for a given **NDC** if both **CapBen_Days** and **QL_Days** are non-blank.
17. For the **Excluded Drug File, if 0 = NO** is entered for **Prior_Authorization_YN,** then **Prior_Authorization_Criteria** must be null.
18. For the **Excluded Drug File, if 1 = YES** is entered for **Prior_Authorization_YN,** then **Prior_Authorization_Criteria** must be populated.
19. For the **Excluded Drug File, if 0 = NO** is entered for **Step_Therapy_YN**, then **Step_Therapy_Criteria** must be null.
20. For the **Excluded Drug File, if 1 = YES** is entered for **Step_Therapy_YN**, then **Step_Therapy_Criteria** must be populated.
21. The **Gap_Cov_YN** variable must be populated and must be equal to 0 or 1. NOTE: this can only be marked as "yes" if the bid includes gap coverage for the tiers on which the excluded drugs reside.

22. Any drugs included in the **Excluded Drug file must be on a tier** that is flagged in the PBP as containing Excluded Drugs (Excluded Drug only tier or combination tier of Part D and Excluded Drugs) in at least one plan.

23. At least one drug must be in the Excluded Drug file for tiers in the PBP that have excluded drugs (either alone or in combination with Part D drugs).

24. At least one drug must be populated with a "1" in the **Gap_Coverage_YN** variable for tiers in the PBP that have excluded drugs (either alone or in combination with Part D drugs) and that include coverage in the gap (either partial or full coverage).

25. The file extension checking method must be consistent with the identified HPMS standard for such checks for the Excluded Drug submission file.

26. The validity of the NDCs submitted on the Excluded Drug supplemental file will be evaluated. This check is performed for all initial submissions and resubmissions. If the NDCs do not match, the submission is rejected.

27. The system stores the time and date when the submission was made (when the "Submit" button is clicked).

28. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.

Over-the-Counter (OTC):

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, **populated**, and **11 characters** in length.
3. All NDCs included in the file must apply to all plans associated with the file. Plans that require different versions of a particular file based on the number of NDCs or the specific drugs covered cannot share the same OTC supplemental file and therefore cannot be linked to the same formulary ID.
4. The **UM_Type** field must be populated and **must be equal to 0 or 1.**
5. If the **UM_Type field is equal to 1**, the **Step_Therapy_Total_Groups, Step_Therapy_Group_Desc, and Step_Therapy_Step_Value** fields must be populated.
6. If the **UM_Type field is equal to 0, the Step_Therapy_Total_Groups, Step_Therapy_Group_Desc, and Step_Therapy_Step_Value** fields must be null.
7. If the **Step_Therapy_Total_Groups** is required, the value **must be a value between and including 1-25.**
8. If the **Step_Therapy_Step_Value** is required, the **value must be equal to 1.**
9. If **Yes** is selected for the question, "Do you cover OTCs as a part of a Step Therapy Protocol submitted for review and approval by CMS?" on the Formulary Information page, then 1 must be entered for the **UM_Type** field for at least one row in the OTC file.
10. If **No** is selected for the question, "Do you cover OTCs as a part of a Step Therapy Protocol submitted for review and approval by CMS?" on the Formulary Information page, then "1" cannot be entered for the **UM_Type** field in the OTC file; **UM_Type must equal 0** for all records.
11. If Yes is selected for the question, "Do you cover OTCs as a part of a Step Therapy Protocol submitted for review and approval by CMS?" on the Formulary Information page, then all **unique** occurrences of the **Step_Therapy_Group_Desc** on the **OTC RxCUI** within the formulary file must exist in the **Step_Therapy_Group_Desc** field in

the OTC file. This step therapy group description validation only occurs when processing the OTC file; validation does not occur when unloading the formulary file.

12. The validity of the NDCs submitted on the OTC supplemental file will be evaluated. This check is performed for all initial submissions and resubmissions. If the NDCs do not match, the submission is rejected.

13. The **extension checking** method must be consistent with the identified HPMS standard for such checks for the OTC submission file.

14. The system stores the **time and date** when the submission was made (when the "Submit" button is clicked).

15. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and rejects submissions if the file contains one or more restricted characters.

Additional Demonstration Drug (ADD):

1. The file must be in a **tab-delimited text** (.txt) format and must not contain a header record.

2. The system validates the **lengths and values** for all fields (see file layout).

3. Each **MMP_NDC** must be unique in the submitted file, populated, and 11 characters in length.

4. **MMP_Tier** must not contain a value greater than the maximum tier number indicated in PBP.

5. **MMP_Tier** must not contain a tier number that is flagged as **'Part D Drug Only Tier'** in the PBP.

6. The **MMP_Tier** field must contain a value of 1 through 6 and cannot be blank. For tier models that only include 2 tiers, the **MMP_Tier** field must only include a value of 1 through 2. For tier models that include 3 or more tiers, the **MMP_Tier** field must only include a value of 3 through 6.

7. The ADD file must contain at least one NDC in each tier defined as a **combo tier** or **Non-Medicare tier** in the PBP.

8. The **MMP_QL_YN** field must be non-blank and contain a value of 0 or 1.

9. If the value is 1 for the **MMP_QL_YN** field, then the **MMP_QL_Amt** and **MMP_QL_Days** fields must be non-blank.

10. If the value is 1 for the **MMP_QL_YN** field, then the **MMP_QL_Amt** field must contain a numeric value of 1 thru 9999.99.

11. If the value is 1 for the **MMP_QL_YN** field, then the **MMP_QL_Days** field must contain a numeric value of 1 thru 365.

12. If the value is 0 for the **MMP_QL_YN** field, then the **MMP_QL_Amt** and **MMP_QL_Days** fields must be null.

13. The **MMP_CapBen_YN** field must be non-blank and contain a value of 0 or 1.

14. If the value is 1 for the **MMP_CapBen_YN** field, then the **MMP_CapBen_Amt** and **MMP_CapBen_Days** fields must be non-blank.

15. If the value is 1 for the **MMP_CapBen_YN** field, then the **MMP_CapBen_Amt** field must contain a numeric value of 1 thru 9999.99.

16. If the value is 1 for the **MMP_CapBen_YN** field, then the **MMP_CapBen_Days** field must contain a numeric value of 1 thru 365.

17. If the value is 0 for the **MMP_CapBen_YN** field, then **MMP1_CapBen_Amt** and **MMP_CapBen_Days** must be null.

18. The **MMP_CapBen_Amt** must be greater than the **MMP_QL_Amt** for a given **MMP_NDC** if both **MMP_CapBen_Amt** and **MMP_QL_Amt** are non-blank.
19. The **MMP_CapBen_Days** field must be greater than the **MMP_QL_Days** field for a given **MMP_NDC** if both **MMP_CapBen_Days** and **MMP_QL_Days** are non-blank.
20. The **MMP_PA_YN** field must be non-blank and contain a value of 0 or 1.
21. If the **MMP_PA_Criteria** field is not null, then the field must not be greater than 3000 characters in length.
22. **MMP_PA_Criteria** must be non-blank if the value is 1 for the **MMP_PA_YN** field.
23. **MMP_PA_Criteria** must be null if the value is 0 for the **MMP_PA_YN** field.
24. The **MMP_ST_YN** field must be non-blank and contain a value of 0 or 1.
25. If the **MMP_ST_Criteria** field is not null, then the field must not be greater than 1000 characters in length.
26. **MMP_ST_Criteria** must be non-blank if the value is 1 for the **MMP_ST_YN** field.
27. **MMP_ST_Criteria** must be null if the value is 0 for the **MMP_ST_YN** field.
28. Each **MMP_NDC** must be unique in the submitted file.
29. **MMP_NDC, MMP_Tier, MMP_QL_YN, MMP_CapBen_YN, MMP_PA_YN,** and **MMP_ST_YN** must be non-blank.
30. The file extension checking method must be consistent with the identified HPMS standard for such checks for the ADD file.
31. The validity of the NDCs submitted on the ADD file will be evaluated. This check is performed for all initial submissions and resubmissions. If the NDCs do not match, the submission is rejected.
32. The system searches for **HPMS restricted characters** (greater than >, less than <, and semi-colon ;) in the upload file and rejects 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		
Sara B. Silver	410-786-3330	sara.silver@cms.hhs.gov
Julia Heeter	410-786-6198	julia.heeter@cms.hhs.gov
Formulary Content & Review Guidelines		
Robert Dombrowski	410-786-5450	robert.dombrowski@cms.hhs.gov
Teisha Robertson	410-786-6567	teisha.robertson@cms.hhs.gov
Part D Formularies Mailbox		partdformularies@cms.hhs.gov
Supplemental File Content		
Mariann Kocsis	410-786-6672	mariann.kocsis@cms.hhs.gov
Part D Benefits Mailbox		partdbenefits@cms.hhs.gov
Supplemental Submissions and Reports		
HPMS Help Desk	1-800-220-2028	hpms@cms.hhs.gov