HEALTH PLAN MANAGEMENT SYSTEM

Medicare Part D Prescription Drug
Formulary Technical Manual

March 28, 2005

Introduction

Since Contract Year (CY) 2001, the Health Plan Management System (HPMS) has provided various utilities to support the submission, review, and approval of the Adjusted Community Rating Proposals (ACRPs) for the Medicare Advantage (MA) organizations, formerly known as Medicare + Choice (M+C) organizations. In CY 2006, the ACRP process was replaced with the Bid submission process, which includes a Formulary submission.

In support of the Medicare Modernization Act (MMA), the Centers for Medicare and Medicaid Services (CMS) enhanced the HPMS to enable prospective Part D organizations to submit their formulary(ies) electronically. This functionality will provide for the upload, receipt, validation, and review of the formulary submission, including all supporting documentation.

The formulary upload functionality will be available March 28, 2005 through April 18, 2005. It is highly recommended that organizations submit their formulary file(s) as early as possible during the upload time frame. Uploading earlier in this time frame will provide organizations with adequate time to address potential upload problems and submit corrected formulary file(s). An organization may resubmit their formulary as many times as necessary during the upload time frame. The final, successful submission will be processed for CMS review. Organizations implementing a drug formulary must provide a formulary file, a required supporting information file that includes the notes, exceptions process description, and long term care conditions of participants and any additional supporting documentation, e.g., prior authorization data and step therapy data. All documentation must be uploaded to HPMS no later than April 18, 2005 at 5:00pm EDT. CMS will review the formulary submission as a part of the overall Bid submission process for CY 2006.

Section I: General Formulary Information

The HPMS formulary upload module will list the contract number(s) for which the formulary upload user is responsible. The formulary upload user will then specify the relationship between each formulary being submitted and the contract number(s). Therefore, the formulary submission could apply to more than one contract number or one contract number could have more than one formulary submission.

Note: During the HPMS Bid/PBP upload process on or before June 6, 2005, users will be required to crosswalk each formulary submission to the contract/plan level. Possible contract-to-plan mappings include: 1) one formulary to one or more plans under a single contract number, and 2) one formulary to plans under multiple contract numbers.

For example:
- Formulary 00001763 maps to H1234 Plan 001;
- Formulary 00001764 maps to H1234 Plan 002;
- Formulary 00001765 maps to S1111 Plan 001, Plan 002, Plan 003 and S1112 Plan 001, Plan 002

During the upload process, organizations will provide the following general information for each formulary submission in the HPMS formulary upload module:

- Associated Contracts – Users will indicate which contract number(s) (H#, R#, S#) are utilizing the specific formulary.
- Formulary Upload Contact – This person who uploads the formulary submission and would work with HPMS staff to resolve any technical issues.
- Formulary Contact - The organization will confirm the Formulary Contact identified in the HPMS Contract Management Module. This person will be the main formulary contact during review and approval and throughout the contract year.
- Formulary Name – This name will be used internally to reference the specific formulary submission. (100 character maximum)
- Number of Cost Share Tiers – This value must be equal to or greater than the highest value indicated in the formulary file. The value would only be greater than the highest value in the formulary file if a tier was excluded from the formulary file and clarified in the required supporting information file. Lastly, this value must equal the number of tiers identified in the Plan Benefit Package (PBP) software submitted on June 6, 2005. (Enter value of 1 - 10)
- Prior Authorization Requirements – If prior authorization is required for certain drugs, the organization should select "Yes" in the HPMS interface. Additionally, the formulary file must identify the drugs that require prior authorization and the organization must upload a prior authorization supporting file.
- Therapeutic Category/Class Database Source – Organizations will indicate the source type for this formulary. The options for this selection are United States Pharmacopeia (USP), American Hospital Formulary Service (AHFS), or a plan defined source.
- Step Therapy Management Program – If one or more drugs are included in a step therapy management program, the organization would answer, "Yes" in the HPMS interface. Additionally, the formulary file must identify the drugs that are part of the step therapy management program and the organization must upload a step therapy supporting file.

Section II: Formulary File Creation Instructions

The formulary file must be created in an ASCII File Tab Delimited format and must contain one record (row) for each NDC. The record layout is provided in Section III: Formulary Record Layout. The file must include at least one NDC record for each drug offered within an organization's benefit plan(s). However, to reduce the burden, organizations are <u>NOT</u> required to include *all* NDCs associated with each drug offered by their plan(s). In most instances, the formulary file will include only one NDC per drug offered by the plan; however, there are some instances where more than one NDC per drug should be included in the formulary file. Multiple NDCs are only required if one or more NDCs for a given drug have differences in tiering, prior authorization, step therapy, and/or quantity limits based on dosage form or strength. Organizations must provide the appropriate supplemental files to expound upon these NDCs/drugs included in the file.

If a given drug has multiple NDCs and some have prior authorization and some do not have prior authorization, the plan must include one NDC without prior authorization along with one or more NDCs that require prior authorization for the same drug.

In conjunction, the Formulary Record Layout in Section III, the Formulary File Field-by-Field Instructions in Section IV, the Formulary File Examples in Section V and the accompanying two sample formulary submission files provide detailed guidance on how to create your formulary submission file. In addition, here are some tips for the creation of a tab-delimited text file:

> - A tab-delimited text file is a special type of text file. Sometimes, "text files" are also referred to as "flat files" or "ASCII files". The phrase "tab-delimited" means that each of the data elements in the file are separated by a tab character. If you are using a text editor such as Notepad, a tab character is created by pressing the <Tab> key. Looking at the "Appendix_1_Example_File_1.txt" sample file, in the first row the NDC field value of "00000354600" and the Tier_Level_Value field value of "2" are separated by a tab character. The tab character may appear to be spaces but the "spaces" are actually created by using the <Tab> key.

> - In the Formulary Record Layout, the Field Length column usually refers to the maximum length of the field value and does not mean that the field value must always be of that length. For example, for the Tier_Level_Value field, the Field Length specification is "2". To specify a value of "1" for "Tier Level 1", put a value of "1" which is only one character in length. Do not pad the value by putting in "01", " 1" or "10". **EXCEPTION:** <u>The only exception to this rule is the NDC field which must always have a length of 11.</u>

> - One method for creating a tab-delimited text file is to enter your information into Excel and then use the "Save As..." function and select "Text (Tab delimited) (*.txt)" for the "Save as type". If you use Excel, each Excel column should represent a separate field as specified in the File Record Layout. If a field is blank, then the corresponding Excel column should be left blank.

Section III: Formulary Record Layout

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

#	Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
1	NDC	CHAR NOT NULL	11	11-Digit National Drug Code	00000333800
2	Tier_Level_Value	CHAR NOT NULL	2	Defines the Cost Share Tier Level Value Associated with the NDC. Assumption is that the NDC is assigned to one tier value. These values are consistent with the selection of value options available to data entry users in the Plan Benefit Package software. If no Tier Level Value applies, enter '1' as the value for this field.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6 7 = Tier Level 7 8 = Tier Level 8 9 = Tier Level 9 10 = Tier Level 10
3	Drug_Type_Label_Value	CHAR NOT NULL	1	Define the Drug Type Label Value for the NDC. Enter the label value for the Drug Type from the defined list of labels in the instructions. If Drug Type Label Value 6 = "Other" is used, then the user must describe the "Other" label description in the Drug_Type_Label_Value_Other field.	1 = Generic 2 = Preferred Brand 3 = Non-Preferred Brand 4 = Non-Formulary 5 = Specialty 6 = Other
4	Drug_Type_Label_Value_Other	CHAR NULL	100	Describe the "Other" label description. If "Other" does not apply, leave this field blank.	Orphan
5	Quantity_Limit_Amount_YN	CHAR NOT NULL	1	Does the NDC have a restriction on the quantity that is available per prescription or a restriction	1 = Yes 0 = No

#	Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
				on the quantity that is available every 30-34 days?	
6	Quantity_Limit_Amount	NUM NULL	3	If Yes to Quantity_Limit_Amount_YN, enter the quantity limit unit amount. The units for this amount may be defined as number of pills, number of injections, etc. If the NDC does not have a quantity limit restriction, then leave this field blank. Entry of whole numbers without leading zeros and decimals is recommended. However, if you choose to use NCPDP standard, use the 9(7)V999 format such as 9999999.999 (e.g., "0000009.000"). Only zeros "0" after the decimal will be accepted. The decimal must be explicitly included; the system will not assume that the last three digits are digits after a decimal. The maximum logical number that will be accepted is "999".	9
7	Quantity_Limit_Days	NUM NULL	3	Enter the days associated with the quantity limit. If the Quantity_Limit_Amount_YN field is 0 = No, then leave this field blank. If the NDC does not have a quantity limit restriction, then leave this field blank. Entry of whole numbers without leading zeros and decimals is recommended. However, if you choose to use NCPDP standard, use the 9(7)V999 format such as 9999999.999 (e.g.,	30 (e.g., 9 pills every 30 days) (e.g., 9 injections every 30 days)

#	Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
				"0000060.000"). Only zeros "0" after the decimal will be accepted. The decimal must be explicitly included; the system will not assume that the last three digits are digits after a decimal. The maximum logical number that will be accepted is "999".	
8	Prior_Authorization_YN	CHAR NOT NULL	1	Is prior authorization required for the NDC?	1 = Yes 0 = No
9	Therapeutic_Category_Name	CHAR NULL	100	If the Category/Class Database Source is indicated as "OTHER" in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user should enter the Therapeutic Category Name for each NDC in the file. If the drug is based on either USP or AHFS Therapeutic Category Classes, then leave this field blank.	Analgesics
10	Therapeutic_Class_Name	CHAR NULL	100	If the Category/Class Database Source is indicated as "OTHER" in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user should enter the Therapeutic Class Name for each NDC in the file. If the drug is based on either USP or AHFS Therapeutic Classes, then leave this field blank.	Opioid Analgesics
11	Formulary_Key_Drug_Type_Name	CHAR NULL	100	*OPTIONAL*: If the Category/Class Database Source is indicated as "OTHER" in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user has the	Opioid Analgesics, long-acting

#	Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
				option to enter the Formulary Key Drug Type (subdivision) Name for each NDC in the file. If the drug is based on either USP or AHFS, then leave this field blank.	
12	Step_Therapy_Type_Group_Num	NUM NULL	2	Number of step therapy drug treatment groups, in which the NDC is included. If Step Therapy does not apply to this drug, then leave this field blank. Entry of whole numbers without leading zeros and decimals is recommended. However, if you choose to use NCPDP standard, use the 9(7)V999 format such as 9999999.999 (e.g., "0000003.000"). Only zeros "0" after the decimal will be accepted. The decimal must be explicitly included; the system will not assume that the last three digits are digits after a decimal. The maximum logical number that will be accepted is "99".	3

The remaining two fields described below should be repeated as a group in the file.

For example, the values for Step_Therapy_Type_Group_Desc_1 = "CHF Therapy" and Step_Therapy_Type_Group_Step_1 = 4 should be included next to each other in the file. Likewise, the values for Step_Therapy_Type_Group_Desc_2 = "Angina Therapy" and Step_Therapy_Type_Group_Step_2 = 1 should be included next to each other in the file. Likewise, the values for Step_Therapy_Type_Group_Desc_3 = "CVD Therapy" and Step_Therapy_Type_Group_Step_3 = 5 should be included next to each other in the file.

#	Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
13	Step_Therapy_Type_Group_Desc_X	CHAR NULL	100	Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num If Step Therapy does not apply to this drug, then leave this field blank.	Step_Therapy_Type_Group_Desc_1 = "CHF Therapy" Step_Therapy_Type_Group_Desc_2 = "Angina Therapy" Step_Therapy_Type_Group_Desc_3 = "CVD Therapy"
14	Step_Therapy_Type_Group_Step_X	NUM NULL	2	Step number within the sequence for the Step Therapy Group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num AND in the same order as Step_Therapy_Type_Group_Desc_X If Step Therapy does not apply to this drug, then leave this field blank. Entry of whole numbers without leading zeros and decimals is recommended. However, if you choose to use NCPDP standard, use the 9(7)V999 format such as 9999999.999 (e.g., "0000004.000"). Only zeros "0" after the decimal will be accepted. The decimal must be explicitly included; the system will not assume that the last three digits are digits after a decimal. The maximum logical number that will be accepted is "99".	Step_Therapy_Type_Group_Step_1 = 4 (e.g., Step 4 of 6) Step_Therapy_Type_Group_Step_2 = 1 (e.g., Step 1 of 3) Step_Therapy_Type_Group_Step_3 = 5 (e.g., Step 5 of 5)

Section IV: Formulary File Field-by-Field Instructions

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

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.

Further clarification regarding the development of the formulary file is provided in Section V – Formulary File Examples and in Attachments 1 and 2. Section V provides an illustration of the formulary layout in MS-word. The attachments are provided in the ASCII Tab Delimited file format for the examples illustrated in Section V.

> ## Field 1 – NDC:
> *REQUIRED*: Each record should include an 11-digit National Drug Code associated with the formulary. The NDC should be in the 5-4-2 format with leading zeros where necessary.
>
> ## Field 2 – Tier_Level_Value:
> *REQUIRED*: Include the cost share tier level value associated with the NDC. Include a value from 1 to 10 only. A number outside of this range will result in an upload error. If cost share tiering does not apply, include the value "1" in this field. NOTE: The maximum value entered for this field may NOT be greater than the value entered for the number of cost share tiers in the HPMS Data Entry Web Interface. If these values are inconsistent, an upload error will result.
>
> *See Section V - Example File 1 and Attachment 1 for an example of how to build a file with three different cost share tier levels.*
>
> ## Field 3 – Drug_Type_Label_Value:
> *REQUIRED*: Include the drug type label value for the NDC. Include a value in this field from 1 to 6 only, where 1 = Generic; 2 = Preferred Brand; 3 = Non-Preferred Brand; 4 = Non-Formulary; 5 = Specialty; and 6 = Other. A number outside of this range will result in an upload error. If 6 = Other is used, then the user must provide the "Other" label in the **Drug_Type_Label_Value_Other** field.
>
> ## Field 4 – Drug_Type_Label_Value_Other:
> *CONDITIONAL*: If the drug type label value is 6 = Other, include a narrative description of the "Other" value in this field. The narrative description included in this field must not exceed 100 characters. If values 1 through 5 are included for the **Drug_Type_Label_Value** field, then leave this field blank by providing a tab delimiter.
>
> *See Section V - Example File 1 and Attachment 1 for an example of how to build a file with a drug type label value of 6 = "Other."*

Field 5 – **Quantity_Limit_Amount_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 NDC has a restriction on the quantity that is available per prescription or a restriction on the quantity that is available every 30-34 days; otherwise set the value to 0 if there are no restrictions other than a one-month supply. Examples of quantity limits include the following:

- Imitrex - 9 tablets/30 days
- Actonel 35mg tablets - 5 tablets/34 days
- Diflucan 150mg tablets - 1 tablet/prescription

If there are multiple limits per NDC, please list the second quantity limit in the notes attachment.

Field 6 - **Quantity_Limit_Amount**:

CONDITIONAL: If the **Quantity_Limit_Amount_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Amount_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 pills or the number of injections for the NDC. For example, for a quantity limit that includes 9 pills every 30 days, this field should indicate a value of 9.

Field 7 - **Quantity_Limit_Days**:

CONDITIONAL: If the **Quantity_Limit_Amount_YN** field is 0, then leave this field blank by providing a tab delimiter. If the **Quantity_Limit_Amount_YN** field is 1, include the quantity limit day amount for this NDC. For example, for a quantity limit that includes 9 pills every 30 days, this field should indicate a value of 30. If there is a quantity limit per prescription (e.g. 1 tablet per prescription), then field should indicate a value of 1.

See Section V - Example File 1 and Attachment 1 for an example of how to build a file containing three NDCs with unique quantity limits.

Field 8 – **Prior_Authorization_YN**:

REQUIRED: This value should be set to value of 0 or 1, where 0 = No and 1 = Yes. Set the value to 1 if the NDC requires prior authorization; otherwise set the value to 0 if prior authorization is NOT required. NOTE: If the user selected **Yes** to the Prior Authorization question in the HPMS Data Entry Web Interface, then one or more NDC records must have a value of 1 for this field. If these values are inconsistent, an upload error will result.

Field 9 – **Therapeutic_Category_Name**:

CONDITIONAL: If the Therapeutic Category/Class Database Source value is "Other, Plan Defined" in the HPMS Data Entry Web Interface, meaning neither the USP nor AHFS therapeutic categories are used by the plan, then include the plan defined therapeutic category name for each NDC in this field. The therapeutic category name included in this field should not exceed 100 characters. If the formulary is based on either USP or AHFS therapeutic categories, then leave this field blank by providing a tab delimiter. However, if the user selects "Other" for the Therapeutic Category/Class Database Source Type question, then all NDC records must include a value for the **Therapeutic_Category_Name** field or an upload error will result.

Field 10 – **Therapeutic_Class_Name**:
CONDITIONAL: If the Therapeutic Category/Class Database Source value is "Other, Plan Defined" in the HPMS Data Entry Web Interface, meaning neither the USP nor AHFS therapeutic classes are used by the plan, then include the plan defined therapeutic class name for each NDC in this field. The therapeutic class name included in this field should not exceed 100 characters. If the formulary is based on either USP or AHFS therapeutic classes, then leave this field blank by providing a tab delimiter. However, if the user selects "Other" for the Therapeutic Category/Class Database Source Type question, then all NDC records must include a value for the **Therapeutic_Class_Name** field or an upload error will result.

Field 11 – **Formulary_Key_Drug_Type_Name**:
OPTIONAL: If the Therapeutic Category/Class Database Source value is "Other, Plan Defined" in the HPMS Data Entry Web Interface, meaning neither the USP nor AHFS key drug type names are used by the plan, then include the plan defined key drug type names for each NDC in this field. The key drug type name included in this field should not exceed 100 characters. If the formulary is based on either USP or AHFS key drug type names, then leave this field blank by providing a tab delimiter. NOTE: If the user selects "Other" for the Therapeutic Category/Class Database Source Type question, then the "Other" key drug type name is optional. If the "Other" key drug type name is not included it will NOT result in an upload error.

See Section V - Example File 2 and Attachment 2 for an example of how to build a file with fields describing "Other" Therapeutic categories.

Field 12 – **Step_Therapy_Type_Group_Num**:
CONDITIONAL: If the user selects **Yes** to having one or more drugs with step therapy management in the HPMS Data Entry Web Interface, then a value must be entered in this field for one or more NDCs. This field should include a value that indicates the number of step therapy drug treatment groups in which the NDC is a member. The value included in this field may not exceed 2 digits in length. If step therapy does not apply to a given NDC, then leave this field blank by providing a tab delimiter. NOTE: If this field is inconsistent with the HPMS Data Entry Web Interface, an upload error will result.

Field 13 – **Step_Therapy_Type_Group_Desc_X**:
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 narrative description of the step therapy drug treatment group. This field should be repeated in the NDC record based upon the number of groups declared in **Step_Therapy_Type_Group_Num**. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter. NOTE: If this field is inconsistent with the HPMS Data Entry Web Interface, an upload error will result.

Field 14 – **Step_Therapy_Type_Group_Step_X**:
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 step therapy drug treatment group it applies to. This field should be repeated in the record based upon number of groups declared in **Step_Therapy_Type_Group_Num** AND in the same order as **Step_Therapy_Type_Group_Desc_X**. If Step Therapy does not apply to this drug, then leave this field blank by providing a tab delimiter. For example, if an NDC for an

Angiotensin receptor blocker has 3 step therapy treatment groups declared in the Step_Therapy_Type_Group_Num field, then three sets of values should be defined for Step_Therapy_Type_Group_Desc_X and Step_Therapy_Type_Group_Step_X as follows:

Step Therapy Treatment Group 1 Values –
Step_Therapy_Type_Group_Desc_1 = "CHF Therapy"
And
Step_Therapy_Type_Group_Step_1 = 4

Step Therapy Treatment Group 2 Values –
Step_Therapy_Type_Group_Desc_2 = "Angina Therapy"
And
Step_Therapy_Type_Group_Step_2 = 1

Step Therapy Treatment Group 3 Values –
Step_Therapy_Type_Group_Desc_3 = "CVD Therapy"
And
Step_Therapy_Type_Group_Step_3 = 5

See Section V - Example File 2 and Attachment 2 for an example of how to build a file with one or more step therapy groups associated with an NDC.

Section V: Formulary File Examples

For each example listed below, the NDCs used are not valid.

Example File 1

Includes the following sample attributes:
1) Three Cost Share Tier Levels
2) "Other" Drug Type Label = 6
3) Three NDCs with Unique Quantity Limits
4) Prior Authorization indicated in HPMS
5) USP Therapeutic Data Source indicated in HPMS
6) No Step Therapy

NOTE: DO NOT INCLUDE A HEADER ROW IN THE ACTUAL FORMULARY FILE. THIS WAS JUST USED IN THE EXAMPLE FOR ILLUSTRATION PURPOSES.

Field 1	Field 2	Field 3	Field 4	Field 5	Field 6	Field 7	Field 8	Field 9	Field 10	Field 11	Field 12	Field 13	Field 14
00000354600	2	6	Orphan Drugs	1	5	30	0						
00000354601	1	3		1	5	30	0						
00000354602	2	6	Orphan Drugs	1	5	30	0						
00000354603	2	6	Orphan Drugs	0			0						
00000354604	3	1		0			1						

Example File 2

Includes the following sample attributes:
1) Three Cost Share Tier Levels
2) Prior Authorization indicated in HPMS
3) "Other" Category/Class Data Source indicated in HPMS
4) One NDC Included with Two Step Therapy Groups

NOTE: DO NOT INCLUDE A HEADER ROW IN THE ACTUAL FORMULARY FILE. THIS WAS JUST USED IN THE EXAMPLE FOR ILLUSTRATION PURPOSES.

Field 1	Field 2	Field 3	Field 4	Field 5	Field 6	Field 7	Field 8	Field 9	Field 10	Field 11	Field 12	Field 13_1	Field 14_1	Field 13_2	Field 14_2
00000354600	2	4		0			0	Analgesics	Opioid Analgesics	Opioid Analgesics, long acting	2	CHF Therapy	4	CVD Therapy	5
00000354601	1	3		0			0	Analgesics	Opioid Analgesics	Opioid Analgesics, long acting					
00000354602	2	4		0			0	Analgesics	Opioid Analgesics	Opioid Analgesics, long acting					
00000354603	2	4		0			0	Analgesics	Opioid Analgesics						
00000354604	3	1		0			1	Analgesics	Opioid Analgesics						

Section VI: Formulary Supporting Documentation

To better facilitate the review process, each supporting formulary file should contain the following applicable identifiers at the top of each page: Contract number(s), Organization name(s), Organization Type(s). The following is an example of a formulary attachment header for multiple contracts:
- H1234 – Health Plan – Local CCP
- R1235 – Healthy Living Plan – Regional CCP
- S1236 – Organization of Health – PDP
- S1237 – Good Health Organization – PDP

In the footer of each page, the page number should be identified in the following format: "Page 1 of 8". Each attachment should be numbered separately.

All attachments should be written in Arial or Times New Roman font with font size of 10-12 point.

Required Supporting Information File Instructions

A formulary upload submission is required to include a required supporting information file that describes the plan's exceptions process, general transition process, long-term care transition process and general notes associated with one or more NDCs on a plan's formulary. This file should be provided in MS-Word format

The file should be divided into four distinct sections with each section clearly identified in the header. CMS requests the file be organized in the following format:
- The first section should contain the Formulary Notes. Plans should include any details that would be important for CMS to consider when reviewing the formulary. This may include special details about certain NDCs that were included in the formulary submission file. Notes should be numbered and grouped alphabetically according to therapeutic category/class.
- The second section should contain the plan's exceptions process. This includes information concerning coverage determinations, exceptions, appeals, timeframes and other important details. These items should be bulleted or numbered.
- The third section should contain the plan's general transition process. Additional details concerning the important elements of this section are contained in the Transition Process guidance.
- The fourth section should contain the plan's long-term care conditions of participation (COP). Additional details concerning the important elements of this section are contained in the Long-Term Care Transition guidance.

Prior Authorization File Instructions

If a formulary has prior authorization for one or more drugs, then a formulary upload submission must include an attachment that describes the specific prior authorization rules. The description of these rules should be provided in MS-Word format.

CMS requests that the prior authorization file be organized in the following format:
- Provide an initial summary page to organize the document, which should contain medications or medication classes that have prior authorization criteria (e.g. Proton pump inhibitors). The medications or medication classes should be listed alphabetically with the associated page number. For example:

> Summary Page
> Actiq   Page 1
> COX-2 inhibitors   Page 2
> Proton pump inhibitors   Page 3

- Following the summary page, each medication or medication class should be listed on the individual pages identified. For example:

> Per the summary page in the previous example, page 1 of the attachment would contain the criteria for Actiq, page 2 would contain the criteria for COX-2 inhibitors, and page 3 would contain the criteria for Proton pump inhibitors.

Step Therapy Algorithm

If a formulary has step therapy for one or more drugs, then a 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 MS-Word format.

CMS requests that the step therapy attachment be organized in the following format:
- Provide an initial summary page to organize the document, which should contain medications or medication classes that have step therapy criteria (e.g. Angiotensin receptor blockers). The medications or medication classes should be listed alphabetically with the associated page number. For example:

> Summary Page
> Angiotensin receptor blockers   Page 1
> Proton pump inhibitors   Page 2

- Following the summary page, each medication or medication class should be listed on the individual pages identified. For example:

> Per the summary page in the previous example, page 1 of the attachment would contain the criteria for Angiotensin receptor blockers and page 2 would contain the criteria for Proton pump inhibitors.

Section VII: Formulary Receipt Confirmation

An HPMS submission confirmation screen will be displayed to the user after all general questions have been answered and submission materials have been uploaded. This does NOT indicate that the upload was successful, only that is was received by the system for further processing.

IMPORTANT NOTE: On the formulary confirmation screen, a unique 8-digit identifier will be assigned to the formulary submission. This ID will be prominently displayed on the HPMS screen. It is critical that the formulary upload user retain the formulary ID for future reference. CMS will utilize this ID throughout the life of the formulary.

The HPMS will send two separate emails to the Formulary Contact and the Formulary Upload Contact regarding the upload and validation status of the formulary submission. The first email will confirm that the formulary was successfully uploaded to the HPMS and will now be passed through the validation process. The second email will be sent after the validation process is complete. The second email will either confirm a successful submission or provide a detailed listing of the error(s) found in the formulary submission. If errors are identified, the organization must correct the errors and perform a successful upload no later than April 18, 2005 at 5:00pm EDT. The errors may be attributed to validation edits or inaccurate data in the formulary file as outlined in these instructions. Please refer to "Section VIII: Formulary Validation Edits" for further details regarding the validation edit checks.

Section VIII: Formulary Validation Edits

After the successful upload of the formulary submission, HPMS will perform a series of validation edit checks. These formulary validation edits are listed below:

- The formulary file is tab delimited and does not contain a header record.

- The **NDC, Tier_Level_Value, Drug_Type_Label_Value, Quantity_Limit_Amount_YN,** and **Prior_Authorization_YN** fields are non-missing.

- Verify that the maximum value for **Tier_Level_Value** field in the formulary file is equal to or less than the number of cost share tiers entered in HPMS data entry.

- Verify that the value for **Drug_Type_Label_Value** field is numeric and has a value of 1 to 6.

- If the **Drug_Type_Label_Value** is **1 - 5**, then verify that the **Drug_Type_Label_Value_Other** field is blank by providing a tab delimiter.

- If the **Drug_Type_Label_Value** is **6 = Other**, then verify that the **Drug_Type_Label_Value_Other** field is non-missing.

- Verify that the **Quantity_Limit_Amount_YN** equals 0 or 1.

- If the **Quantity_Limit_Amount_YN** is **1 = Yes**, then verify that the **Quantity_Limit_Amount** field is a non-missing numeric value from 1 - 999.

- If the **Quantity_Limit_Amount_YN** is **1 = Yes**, then verify that the **Quantity_Limit_Days** field is a non-missing numeric value from 1 - 999.

- Verify that the **Prior_Authorization_YN** equals 0 or 1.

- In the HPMS data entry, if the formulary upload user indicated that prior authorization exists, (e.g. answered "Yes**"** to the prior authorization upload question), then verify that at least one record has a **1 = Yes** value for the **Prior_Authorization_YN** field in the formulary file.

- In the HPMS data entry, if the formulary upload user indicated that prior authorization does not exist (i.e. answered "No**"** to the prior authorization upload question), then verify that ALL records have a value of **0 = No** for the **Prior_Authorization_YN** field in the formulary file.

- In the HPMS data entry, if the formulary upload user selected **Other** for the Therapeutic Category/Class Database Source Type question, then verify that the **Therapeutic_Category_Name** and **Therapeutic_Class_Name** are non-missing.

- In the HPMS data entry, if the formulary upload user selected **USP** or **AHFS** for the Therapeutic Category/Class Database Source Type question, then verify that the

Therapeutic_Category_Name, **Therapeutic_Class_Name**, and
Formulary_Key_Drug_Type_Name fields are blank by providing tab delimiters.

- In the HPMS data entry, if the formulary upload user indicated that step therapy does exist (i.e. answered "Yes" to the step therapy upload question), then validate that at least one record includes non-missing values for **Step_Therapy_Type_Group_Num**, **Step_Therapy_Type_Group_Desc_X**, and **Step_Therapy_Type_Group_Step_X** in the formulary file.

- In the HPMS data entry, if the formulary upload user indicated that step therapy does not exist (i.e. answered "No" to the step therapy upload question), then validate the **Step_Therapy_Type_Group_Num**, **Step_Therapy_Type_Group_Desc_X**, and **Step_Therapy_Type_Group_Step_X** fields are blank by providing tab delimiters.

- If the **Step_Therapy_Type_Group_Num** field is non-missing, then validate that it is a numeric value from 1 - 99.

- Verify that the number of pairs of **Step_Therapy_Type_Group_Desc_X** and **Step_Therapy_Type_Group_Step_X** equal the number indicated in **Step_Therapy_Type_Group_Num**.

- For the four numeric fields, **Quantity_Limit_Amount, Quantity_Limit_Days**, **Step_Therapy_Type_Group_Num** and **Step_Therapy_Type_Group_Step_X**, verify that no values have leading zeros, end with "000," or contain a decimal.

Section IX: List of Contacts

HPMS Technical Help Desk   1-800-220-2028   hpms@nerdvana.fu.com

HPMS
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    Ana Nunez-Poole   410-786-3370   anunezpoole@cms.hhs.gov

Formulary Content & Review Guidelines
    Aaron Eaton   410-786-2058   aeaton2@cms.hhs.gov
    Babette Edgar   410-786-0400   bedgar@cms.hhs.gov