DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

TO: All Part D Sponsors

FROM: Jennifer R. Shapiro, Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: CY 2016 Formulary Information

DATE: January 19, 2016

This memorandum describes the process for submitting formulary updates for the 2016 contract year. Sponsors are reminded that the earliest effective date to implement approved negative formulary changes is March 1, 2016. Negative formulary change requests were able to be submitted via the Health Plan Management System (HPMS) Negative Formulary Change Request (NCR) Module beginning on December 31, 2015. Only approved negative changes may be implemented. Please note that for CY 2016, the deadline to submit both maintenance and non-maintenance HPMS NCRs is July 31, 2016.

CY 2016 Formulary Update Process

Q1: When are the formulary submission windows for CY 2016 formulary updates?

A1: The CY 2016 formulary submission windows are listed below, along with the dates that the corresponding updates to the CY 2016 Formulary Reference File (FRF) will be available in the CY 2016 HPMS Formulary Submission Module. The submission window begins at 12:00 AM ET on the opening date and closes at 11:59 PM PT on the closing date. Any formulary submission that is not successfully uploaded and validated prior to the submission deadline will be denied.

Any difficulties encountered upon upload or validation of your formulary should be brought to the attention of CMS and/or the HPMS help desk prior to the window closing. For technical issues, contact the HPMS help desk at (800) 220-2028 or hpms@cms.hhs.gov. For other issues, please contact CMS at PartDFormularies@cms.hhs.gov. No consideration will be given for late submissions due to technical difficulties unless HPMS assistance was sought in ample time to troubleshoot the problems before the deadline.

CY 2016 FRF Release Date	Formulary Submission Window
January 25, 2016	February 1 – 3, 2016
February 23, 2016	March 1 – 3, 2016
March 25, 2016	April 1 – 5, 2016
April 25, 2016	May 2 – 4, 2016
May 24, 2016	June 1 – 3, 2016
June 24, 2016	July 1 – 6, 2016
July 25, 2016	August 1 – 3, 2016
August 25, 2016	September 1 – 6, 2016
September 26, 2016	October 3 – 5, 2016

Q2: Will CMS utilize the line-level review process for CY 2016 formulary updates?

A2: Yes. Part D sponsors will continue to submit partial formulary update files and we will perform line-level reviews on these updates. Partial files must be submitted during the aforementioned formulary submission windows. We will review changes at the individual RXCUI level, as opposed to the file as a whole. If a sponsor submits a partial formulary update file that is fully acceptable, there is no need for the line level resubmission process and as such the sponsor will not receive a communication notifying them of the need to complete this process. Plan sponsors will need to access the Line Level Accept/Reject page in HPMS for partial formulary update file submissions that are considered only partially acceptable. Upon Part D sponsors' acceptance of our line-level decisions, HPMS will create a new version of the formulary containing only the allowable changes. In the event that a sponsor denies the CMS line-level review decisions, the entire formulary will be denied and the formulary will revert back to the most recently approved version in HPMS (i.e., it will not contain any of the CMS-approved line-level changes submitted). The following chart details the dates for CMS' review of line-level changes and the corresponding dates that Part D sponsors must take action on the review. **Formulary files that contain a significant number of non-allowable changes will be denied.**

Line-Level Decisions Available to Plans	Plan Deadline to Accept/Deny CMS Line-Level Decisions
February 17, 2016	February 18, 2016
March 16, 2016	March 17, 2016
April 20, 2016	April 21, 2016
May 18, 2016	May 19, 2016
June 15, 2016	June 16, 2016
July 20, 2016	July 21, 2016
August 17, 2016	August 18, 2016
September 21, 2016	September 22, 2016

October 19, 2016	October 20, 2016

Q3: When should new drugs within the protected classes be added to the HPMS formulary file?

A3: New drugs or newly approved uses for drugs within the protected classes must be added to the formulary by the end of the 90 day expedited review period. If this time period does not exactly coincide with an HPMS formulary submission, the drug must be included on the HPMS formulary file during the next available submission window. For example, if a new drug within the protected classes is available on the market on May 8, 2016, the P&T committee must review the drug and add it to the formulary for adjudication by August 6, 2016. The drug must then be added to the HPMS formulary file during the September 1-6, 2016 submission window. **Failure to add a protected class drug, or the addition of a protected class drug to the formulary with a non-allowable tier placement or non-allowable utilization management (UM) during the required HPMS formulary submission window will result in denial of the formulary file, suppression of the formulary in Medicare Plan Finder (MPF) and may result in a compliance action.**

Q4: What types of changes can be made to the HPMS formulary files?

A4: Only allowable enhancements, as outlined in Appendix A, and CMS-approved negative changes may be included in updated HPMS formulary files starting with the February 2016 submission window.

Although the formulary submission window is limited, formulary enhancements, such as adding a Part D drug to the formulary, may be implemented at any time. Consistent with section 60.5 of the Medicare Marketing Guidelines, the enhancements must be included in the Part D sponsor's marketing materials. The marketed formulary enhancements must then be reflected in the next HPMS formulary submission. In addition, sponsors are encouraged to directly notify beneficiaries of formulary additions in a timely manner since in some cases, such as new generics, an earlier conversion could lead to better value for the beneficiary and potentially reduce program costs.

CMS-approved negative changes for the current contract year submitted through the HPMS NCR Submission module should be reflected in the formulary file update submitted in the month preceding the proposed NCR effective date. For example, if the intended negative change effective date is May 1, 2016, then the proposed NCR should be sent to CMS on or before March 1, 2016. If the NCR is approved, the negative change should be reflected in the partial formulary file update uploaded during the April 1-5, 2016 formulary submission window.

Additional negative changes submitted that did not receive prior approval will be denied by CMS via the line-level review process. Any non-allowable negative changes may not be implemented or marketed. The most common reasons that would result in our denial of submitted formulary changes are: changes in the therapeutic category and/or pharmacological class name; tier increase or deletion of a drug without an approved NCR; addition of a drug to the specialty tier that does not meet the specialty tier cost threshold; addition of UM to an existing drug without an approved NCR; inappropriate UM type for protected classes drugs (e.g., not limited to new starts only); and missing new protected classes drug(s). We expect plan sponsors to perform internal quality assurance checks on the formulary files to identify unintended negative formulary changes prior to submission in HPMS.

Q5: How does CMS evaluate negative formulary change requests?

A5: Negative formulary change requests are reviewed in accordance with the midyear formulary change policy outlined in section 30.3.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. The vast majority of change requests that are submitted for review are maintenance changes typically involving negative changes to a brand name drug with corresponding addition of an equivalent generic. These types of changes may be applied to all enrollees following the required approval and notification processes. In contrast, as per section 30.3.3.3, non-maintenance changes (e.g., changing preferred or non-preferred formulary drugs, adding utilization management, increasing cost sharing on preferred drugs, removing dosage forms, or exchanging therapeutic alternatives), can only be applied to those enrollees not currently taking the affected drug. When sponsors submit non-maintenance requests for review, a corresponding clinical justification that supports the change must also be submitted. In order for CMS to approve a non-maintenance change, the formulary must continue to satisfy the minimum formulary requirements established by CMS and the proposed change must not substantially discourage enrollment by certain beneficiary groups.

Q6: Are Part D sponsors permitted to make changes to their existing prior authorization (PA) or step therapy (ST) criteria?

A6: Yes, but only in limited circumstances. Generally, a sponsor should not need to make significant revisions to its approved criteria during the contract year. As per 42 CFR §423.120(b)(vi), submitted UM criteria should already have been evaluated for clinical accuracy by the P&T committee prior to submission of the formulary to CMS. It is our expectation that Part D sponsors will not need to update criteria except under extraordinary circumstances, such as when new drug safety-related information becomes available during the contract year (e.g., a new Black Box warning). Revisions should be limited in scope as opposed to a significant rewrite of existing criteria. Part D sponsors are expected to perform all necessary quality assurance checks on formulary files prior to

HPMS submission. As a result, criteria changes to correct spelling or grammatical errors, for example, will not be accepted.

As detailed below, plan sponsors are required to submit a request to CMS before making changes to existing PA or ST criteria, regardless of whether the sponsor considers the change to be a restriction or an enhancement.

Q7: How do Part D sponsors submit changes to existing PA or ST criteria?

A7: Sponsors will continue to utilize the UM Criteria Change Request template (attached) when there is a need to change existing PA or ST criteria. We must receive an accurately completed template by the stated deadline to ensure that criteria gates are opened for submission. The following steps detail the submission process:

1. Complete the UM Criteria Change Request template for the applicable formulary IDs and ST or PA group descriptions. The group descriptions included on the template must match exactly the group descriptions from the formulary file. The reason for change field must be completed by selecting a specific reason for the change from the drop down options. Please note, the reason options have changed for CY 2016 in order to better characterize the extraordinary circumstance described above. A justification describing the rationale for the change is also required. Please note that multiple formularies may be listed on a single worksheet. The template must be completed as follows:
    a) **CY 2016 Formulary ID (FID):** enter only one valid 5-digit CY 2016 formulary ID per line item. However, you may enter more than one FID per template.
    b) **Reason for UM Change:** from a drop down menu, select Removal of a restriction, Addition of drug(s) to existing criteria, Addition of a new indication, Restriction based on a new Black-Box Warning/FDA Safety Communication, or Other extraordinary circumstance. .
    c) **Current UM Type:** from a drop down menu, select PA type 1, 2 or 3 or ST type 1 or 2.
    d) **Current UM Group Description:** enter the Group Description from the last approved formulary and PA or ST text files. This field will be pre-populated with an "NA" if the current PA type is 3 and should not be modified.
    e) **PA Criteria Element (N/A for ST Criteria):** from a drop-down menu, select the PA criteria element for which you will be adding revised or new PA criteria. Only one PA element may be selected for each line item. If you will be modifying multiple PA criteria elements for the same formulary ID and PA group description, you will enter these elements on successive rows of the template. PA criteria elements are described in the CY 2016 HPMS Formulary Submission Module and Reports Technical Manual. Please note

the character limitations for each element. Any criteria that exceed authorized character limitations as noted in the record layout will be rejected.

f) **Justification for UM Change:** enter the justification for the proposed UM change(s). Please include pertinent references such as new safety warnings to support proposed changes, as applicable.

2. Submit the completed template to the CMS UM Criteria Requests mailbox (umcriteriarequests@cms.hhs.gov) no later than 12:00 PM (NOON) ET on the last business day prior to the monthly formulary gate opening date. The subject line of the email should read "CY 2016 UM Criteria Request—Formulary ID XXXXX".
3. Upon receipt of the completed templates, we will open the applicable PA and ST group descriptions gates so that criteria revisions may be submitted by plan sponsors.
4. Sponsors will submit the monthly formulary update partial file during the regularly scheduled formulary submission window, along with the updated ST and/or PA criteria partial files.

Q8: How will CMS review revised and newly submitted UM criteria?

A8: After criteria have been submitted via HPMS, we will review them for clinical appropriateness. Based on this review, we may require sponsors to update their files. This process has not changed for CY 2016; however we are providing additional clarification as CMS has observed instances where sponsors have required multiple resubmissions to achieve compliance with Part D program requirements. Due to short review timeframes and because beneficiaries need access to accurate information, sponsors will be allotted a limited number of opportunities to revise their criteria based upon CMS feedback. Criteria elements that remain unacceptable will revert back to the previously approved criteria or be removed, absent extraordinary circumstances.

We will also review revised criteria to ensure that changes are limited to those that were requested in advance and that extraordinary circumstances exist which would warrant change. If extraordinary circumstances do not exist, criteria will not be reviewed and must revert back to the previously approved criteria. If sponsors make additional changes to the criteria text files, their organizations may be subjected to a compliance action by CMS.

Q9: What is the process for submitting supplemental formulary files (free first fill, partial gap or home infusion) with each formulary upload?

A9: During the monthly update windows, sponsors must indicate in HPMS whether they will be using the previously uploaded versions of these documents or if they will be uploading a new file(s). Sponsors must submit a new version of the file(s) only if there are changes in the list of drugs that have supplemental coverage. If there are no changes, sponsors must indicate that they are using their previous file(s). Please note that if a new

supplemental file is uploaded and the file contains non-allowable changes, the affected plan(s) will be suppressed in the MPF until a corrected supplemental file is uploaded. Examples of non-allowable changes to supplemental formulary files are outlined in Appendix A.

For those formularies that are associated with a Partial Gap, Free First Fill or Home Infusion Supplemental Files, plan sponsors have the option to indicate whether changes are required to the Supplemental Files when they accept CMS review decisions via the line level process. If a plan sponsor indicates that no changes are required, then the system will continue to use the previously uploaded supplemental file. If a plan sponsor indicates that changes are required, the user will be prompted via email to upload new files. New supplemental files must be uploaded by 11:59 PM PT on the same day as the formulary resubmission line level closing date. **Failure to upload the required supplemental files may result in a compliance action.**

Q10: How should Part D sponsors coordinate formulary submissions and MPF pricing file submissions?

A10: Plan sponsors are reminded that MPF pricing files must contain pricing for all drugs included in their current CMS-approved formulary. Since formulary submission dates and MPF pricing file submission dates differ, it is imperative that plan sponsors continuously refer to the MPF operational calendar to ensure the coordination of formulary and pricing updates. For example, formulary updates submitted between February 1 and February 3, 2016 will be reviewed for approval by February 23, 2016. Plan sponsors should prepare MPF pricing files to include information reflecting these formulary changes for submission to DestinationRx from February 29-March 1, 2016. If the submitted formulary file is not approved by 11:59 PM EST on February 23, 2016, plan sponsors should submit MPF pricing files reflective of the previously approved formulary.

Appendix A

Formulary File Enhancements
1. Addition of Part D drugs, with or without UM
2. Moving drugs to a more favorable beneficiary cost-sharing tier
3. Removal of prior authorization (PA) requirements
4. Changing PA Type from 1 (PA applies) to 2 (PA applies to new starts only) or 3 (Part B versus Part D PA only, if a Part B versus Part D PA is appropriate)
5. Removal of quantity limit restrictions
6. Making existing quantity limits less restrictive (e.g., increasing the allowable quantity limit amount without changing the quantity limit days supply)
7. Step therapy (ST) enhancements: • Removal of entire ST protocol (e.g., removal of step therapy requirements for the stepped drug(s) and the corresponding removal of step edits from all prerequisite drugs) • Removal of ST requirements for a drug(s) within the highest step level of a protocol (e.g., removal of step requirements for one step 2 drug within a step therapy protocol containing two step levels and more than one step 2 drug) • Addition of prerequisite step 1 drugs to existing ST protocols (i.e., the new step 1 drug *or* the existing step 1 drugs would qualify the member for the step 2 drug) • Changing ST Type from 1 (ST applies) to 2 (ST applies to new starts only)
Negative Formulary File Changes
1. Removal of FRF RXCUIs
2. Moving drugs to a less favorable beneficiary cost-sharing tier
3. Addition of any UM edits to existing formulary drugs (except for the addition of step 1 edits to prerequisite drugs in existing or new step therapy protocols, as outlined above)
4. Making existing quantity limits more restrictive (e.g., decreasing the allowable quantity limit amount without changing the quantity limit days supply OR increasing the quantity limit days supply without changing the quantity limit amount)
Non-Allowable Changes
1. Change in formulary model/classification
2. Change in the formulary file category or class names for existing formulary drugs
3. Addition of RXCUIs to a specialty tier that do not meet the cost criteria as outlined in the CY 2016 Call Letter
5. Removal of prerequisite (e.g., Step 1 drugs) from existing step therapy protocols
6. Addition of a limited access indicator to an existing formulary drug