



Center for Drug and Health Plan Choice

TO: All Part D Plan Sponsors

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

RE: August Limited Updated Window for CY 2009 Formulary Submissions

DATE: August 5, 2008

2009 Formulary Timelines and Processes

CMS is currently in the process of granting conditional approvals for CY2009 formularies. Those formularies that still have outstanding issues will be contacted by CMS to schedule a negotiation call. CMS will make every effort to accommodate all negotiation requests within the existing time and resource constraints at this stage of the 2009 formulary review process. Given those constraints, organizations must understand that those formularies with limited issues that can be addressed during a brief discussion with CMS are more likely to receive full CMS consideration than those formularies with complex issues requiring extensive discussions.

CMS reminds all plans of the importance of resolving any outstanding formulary concerns in an expeditious manner. Formularies that do not receive conditional approval by August 14, 2008, will not be eligible for the August limited update window. No exceptions will be granted.

Part D sponsors must have a conditionally, approved formulary to be eligible for a CY 2009 Part D contract. As stated on page 56 of the 2009 Call Letter, Part D sponsors that fail to meet formulary submissions and resubmission deadlines during the 2009 contract year formulary approval process may face a CMS determination that we cannot approve their 2009 Part D bids.

We would also note that organizations that failed to meet CY2009 Stage 1, 2 or 3 formulary review resubmission deadlines and those organizations whose formulary resubmissions contained negative changes will be reviewed after CMS completes its review of all other timely formulary submissions.

Part D sponsors must resolve all outstanding issues and receive conditional approval for their CY2009 formulary no later than 5:00pm EDT on September 4, 2008. Any Part D sponsor that has not received conditional approval of its CY2009 Part D formulary by September 5, 2008 will not have its plan included in the Medicare and You Handbook. Also, the Part D sponsor may not receive a Part D contract, making it ineligible to offer Part D benefits during CY2009.

August Limited Update Window for CY 2009 Formulary Submissions

Part D sponsors will have the opportunity to make updates meeting certain criteria to their conditionally approved CY 2009 formulary submissions from 12:00 AM EDT August 11, 2008 through 6:00 PM EDT August 14, 2008. This will be the only opportunity to make negative changes to your CY 2009 formulary submission(s) prior to March 1, 2009. Only formularies that have received prior conditional CMS approval will be permitted to submit an update during this period. An updated CY 2009 Formulary Reference File (FRF) will be available within the CY 2009 HPMS formulary submission module the week of August 4, 2008. Only proxy NDCs included within this file can be submitted to HPMS.

The August update window cannot be used for making significant changes to conditionally approved formulary submissions and will be limited to the allowable types of changes described in this guidance. In order to ensure the timely review and approval of updates made in accordance with this guidance, CMS will not review updated formulary submissions that include changes other than the allowable changes described in this guidance. If non-allowable changes are included, inadvertently or not, the entire formulary update will be rejected and the last conditionally approved formulary submission will instead be considered the final CY 2009 formulary submission. No exceptions will be granted and, therefore, we strongly encourage Part D sponsors to perform sufficient quality assurance checks prior to submitting files to CMS. Allowable and non-allowable changes to CY 2009 formulary submissions during the August limited update window are shown in Attachment 1.

In order to facilitate the review, all allowable negative formulary changes (see Allowable Changes table 2,3, and 5) must be identified in the attached “Formulary Change” template. The template facilitates CMS’ identification and confirmation of the required relationship between the associated negative changes and corresponding generic availability or enhancement. The failure to identify allowable offsetting changes in the template will delay the review process and may result in formulary submissions being rejected. The instructions regarding how to complete the “Formulary Change” template are outlined in Attachment 2.

During the update window, Part D sponsors should select the “Formulary Revision” option in HPMS and utilize the “Updates” section. Sponsors may upload and validate a formulary only once during the open window period and the upload must include any prior authorization and step therapy attachments if the formulary contains such requirements. These formulary attachments must match utilization management edits (e.g. PA, QL, and ST requirements) indicated on the flat file submission. Failure to upload or failure to provide updated documents that match the formulary file may result in rejection of the submission.

Following the update window, Part D sponsors must check the status of formulary approvals in HPMS. Only approved formularies can be marketed beginning October 1, 2009. The Medicare Prescription Drug Plan Finder will be suppressed for original or updated formulary submissions that have not yet been approved. For these reasons, CMS emphasizes that Part D sponsors should not attempt to make significant numbers of changes because it could delay approval of their formulary updates.

If you have any questions regarding this limited update window, please email the Part D Formularies mailbox (PartDformularies@cms.hhs.gov).

Attachment 1.

Allowable Changes	
1. Formulary enhancements:	<ul style="list-style-type: none">• Addition of drugs (with or without utilization management requirements)• Removal of utilization management requirements• Moving drugs to more favorable beneficiary cost sharing tiers• Changing PA type from 1 to 2 or 3 (if a Part B versus D PA is appropriate)• Changing PA type from 2 to 3 (if a Part B versus D PA is appropriate)• Changing ST type from 1 to 2• Changing the ST step value from a value of greater than 1 to 1• Increasing the allowable quantity limits (e.g. increasing the QL amount without changing the QL days)
2. Offsetting brand/generic substitutions:	A brand-name drug removal, addition of prior authorization, step therapy, or change to less favorable beneficiary cost-sharing when an A-rated generic or multi-source brand equivalent is already on or added to the formulary at a more favorable beneficiary cost-sharing tier and less restrictive utilization management requirements than the affected brand product
3. Offsetting therapeutic substitutions within classes:	Limited changes to formulary drugs will be allowed when offset by a change in the status of a drug from the <u>same USP Model Guidelines v4.0 Pharmacologic Class</u> . Specifically, these allowable changes include: <ul style="list-style-type: none">• Formulary deletion with a corresponding addition of a drug within the same USP class, at the same or lower beneficiary cost-sharing, with the same or less restrictive utilization management restrictions, or• Increase in beneficiary cost-sharing of a formulary drug when another drug from the same USP class is moved to a lower cost-share tier
4. Removal of drugs based upon the August update to the CY 2009 Formulary Reference File (FRF)	
5. Addition of prior authorization only for:	<ul style="list-style-type: none">• Part B vs. D coverage determinations, or• New FDA Black Box Warning
6. Addition of step therapy if the Step_Therapy_Step_Value is 1 (i.e. prerequisite drugs) to newly added drugs or drugs currently existing on the conditionally approved formulary	
Non-Allowable Changes	
1. Addition of new quantity limit restrictions, or changes in the quantity limit amount or days of formulary drugs that results in a more restrictive quantity limit than what was previously approved	
2. Addition of any prior authorization requirements NOT described above	
3. Addition of step therapy requirements to drugs currently existing on the conditionally approved formulary, other than adding a step 1 “prerequisite” designation	

4. All deletions, or changes to a less favorable beneficiary cost-sharing tier, that are unrelated to offsetting brand/generic or therapeutic substitutions or FRF deletions, as described above

5. Changes to the CY 2009 categories and classes (including changes to the spelling, punctuation, or other characters within the therapeutic category and pharmacologic class fields for any formulary drug)

Attachment 2. Instructions for completing the “Formulary Change” Template

Blank fields on the template are considered required fields and must be completed to be considered for review by CMS. For each blank field on the template please provide the appropriate data as described below (cells pre-populated with “NA” do not require additional data entry):

1. Formulary ID: enter a valid four digit CY 2009 formulary ID (preceding zeros should be omitted). **Only one formulary ID can be entered per field and per template.** Multiple formulary IDs submitted on a single template will result in the rejection of the entire template and will delay the review of your file.
2. Type of Change: select a type of change designation from the drop down menu in this field.
3. Proxy Code: enter an 11 digit proxy code that exists on the CY 2009 FRF. This code should not contain dashes, spaces or other characters. Please ensure that the proxy code data is formatted as text to prevent the loss of leading zeros. Templates submitted with truncated proxy codes due to the loss of leading zeros will be rejected and may delay the review of your resubmission.
4. Affected brand name, generic name, dosage form, route and strength: enter the appropriate drug information in each cell that relates to the specified proxy code. The data submitted in these cells must match exactly the data found in the CY 2009 Formulary Reference File.
5. Tier (as applicable): enter a number from 1-10 that corresponds to the current and/or proposed tier for the affected drug.
6. Offsetting CY 2009 FRF proxy code, brand name, generic name, dosage form, route, strength and tier (as applicable): these fields must be completed for each formulary change that requires an offsetting action.
7. Justification (as applicable): enter a brief explanation for why the selected type of change is being requested.

The completed template should be submitted to the Part D Formularies mailbox (PartDformularies@cms.hhs.gov) between 12:00 AM EDT on August 11, 2008 and 6:00 PM EDT on August 14, 2008. The template worksheet should be copied or forwarded in its entirety to maintain formatting integrity. The template file name and the subject header line of the email submission should use the following format: **CY09FormularyChangeTemplate_IDxxxx**. The four digit ID number should reflect the formulary ID for which changes are being requested. Only the information found in the “Formulary Change Template” will be considered in the review of your submission. Any altered, recreated, or improperly completed templates will be rejected.