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

CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

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

SUBJECT: August Limited Update Window for CY 2011 Formulary Submissions

DATE: July 30, 2010

CY 2011 Formulary Timelines and Processes

CMS is currently in the process of granting conditional approvals for CY 2011 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 2011 formulary review process. Given those constraints, organizations must understand that those formularies with limited issues will receive the first negotiation calls and as a result be more likely to be eligible for the August update window. 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 18, 2010, 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 2011 Part D contract. Consistent with the CY 2010 Call Letter (page 56), Part D sponsors that fail to meet formulary submissions and resubmission deadlines during the 2011 contract year formulary approval process may face a CMS determination that we cannot approve their 2011 Part D bids. Organizations that failed to meet CY 2011 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.

Any Part D sponsor that has not received conditional approval of its CY 2011 Part D formulary by September 2, 2010 will not have its plan included in the Medicare and You Handbook. Part D sponsors must resolve all outstanding issues and receive conditional approval for their CY 2011 formulary no later than 5:00 P.M. EDT on September 5, 2010. Failure to attain conditional approval by this deadline may result in the Part D sponsor not receiving a Part D contract, making it ineligible to offer Part D benefits during CY 2011.

August Limited Update Window for CY 2011 Formulary Submissions

Only formularies that have received prior conditional CMS approval will be permitted to submit an update during the August update window. Part D sponsors will have the opportunity to make updates that meet certain criteria (See Attachment 1) to their conditionally approved CY 2011 formulary submissions from 12:00 A.M. EDT August 16, 2010 through 6:00 P.M. EDT August 18, 2010. This will be the only opportunity to make negative changes to your CY 2011 formulary submission(s) prior to March 1, 2011. An updated CY 2011 Formulary Reference File (FRF) will be available within the CY 2011 HPMS formulary submission module on August 9, 2010. Only RXCUIs 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. Changes must be limited to the allowable types of changes described in Attachment 1. 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 2011 formulary submission. No exceptions will be granted. We strongly encourage Part D sponsors to perform adequate quality assurance checks prior to submitting files to CMS.

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 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 prior authorization (PA) and step therapy (ST) text files if the formulary contains such requirements. Changes to PA and ST criteria files must be limited to the addition of criteria for drugs being added to the formulary and removal of criteria for drugs that no longer require PA or ST or for drugs being removed from the formulary. 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, 2010. Original or updated formulary submissions that have not yet been approved will be suppressed in the Medicare Prescription Drug Plan Finder. 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 and Non-Allowable Changes

Allowable Changes
1. Formulary enhancements: • 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 same USP Model Guidelines v4.0 Pharmacologic Class. Specifically, these allowable changes include: • 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 2011 Formulary Reference File (FRF)
5. Addition of prior authorization only for: • 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 2011 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 five digit CY 2011 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. RXCUI: enter a 5 or 6 digit RXCUI that exists on the CY 2011 FRF. This code is numeric only (preceding zeroes should be omitted) and should not contain dashes, spaces or other characters.
4. Affected brand name (where applicable), SCDC, and dose form: enter the appropriate drug information in each cell that relates to the specified RXCUI. The data submitted in these cells must exactly match the data found in the CY 2011 Formulary Reference File (FRF).
5. Tier (as applicable): enter a number from 1 – 6 that corresponds to the current and/or proposed tier for the affected drug.
6. Offsetting CY 2011 FRF RXCUI, brand name (where applicable), SCDC, dose form, 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 A.M. EDT on August 16, 2010 and 6:00 P.M. EDT on August 18, 2010. 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: **CY11FormularyChangeTemplate_IDxxxxx**. The five digit ID number should be 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.