DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-16-16
Baltimore, Maryland 21244-1850

Center for Beneficiary Choices

MEMORANDUM

TO: All Part D Plan Sponsors

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

RE: Updating CY 2007 and CY 2008 Formularies

DATE: June 20, 2007

The Part D formulary submission and approval process requires a cooperative effort between CMS and Part D plans to ensure that all Part D formularies comply with CMS requirements. CMS requirements state that Part D plans should not view their initial formulary submissions for the upcoming contract year (i.e. 2008) as preliminary. CMS expects Part D plans to design, perform appropriate quality assurance, and submit formularies for the upcoming contract year that represent final products.

Nevertheless, we recognize that it is in the best interest of Medicare beneficiaries to allow Part D plans to appropriately manage formularies and make improvements prior to and during the contract year. However, CMS' ability to provide an opportunity to make such improvements prior to marketing and enrollment for the following contract year is highly dependent upon Part D sponsors' compliance with CMS requests to address areas of concern, as well as adherence to CMS guidance on allowable types of changes. Failure to provide necessary information or modifications and/or incorporating unauthorized changes delays the entire review process and, ultimately, the attainment of a conditionally approved formulary.

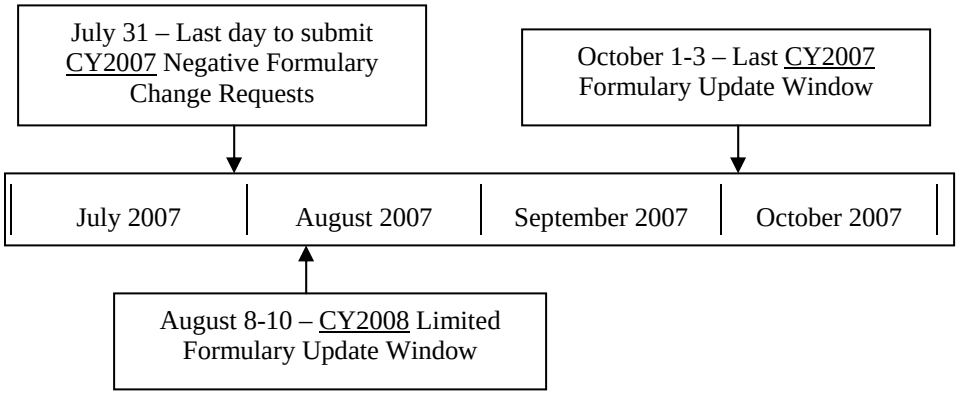
Part D sponsors should understand that the submission and evaluation of CY2007 negative change requests runs concurrently with the CY2008 initial formulary review process. In order to accommodate Part D plans that want to update their formularies for next year (2008), and to also provide sufficient time to review and approve remaining mid-year negative formulary change requests for the current year in time for the final MPDPF update of formulary information (September 10, 2007), CMS is:

- Establishing a July 31st deadline for negative formulary change requests for the formularies in effect for the current year (2007); and
- Establishing an August update window for those Part D plans that want to make changes to their formularies for next year (2008). In order to ensure the timely review and approval of August changes, CMS will be limiting the types of changes that can be made during this update window.

I. CY 2007 Negative Formulary Change Request Submission Deadline

The last date to submit negative formulary change requests for CY 2007 is July 31, 2007, 11:59 pm EDT. Any change requests submitted after this date will not be considered for review by CMS. The October 2007 formulary submission window will be the final opportunity to upload changes to the CY 2007 formulary. In addition, CMS prioritizes maintenance change requests over non-maintenance change requests and can only guarantee that maintenance change requests received through July 31st, 2007 will be reviewed. Plans should limit their non-maintenance changes. CY 2007 non-maintenance negative change requests that are not reviewed and approved prior to the October window cannot be implemented by Part D sponsors. Part D sponsors may continue to enhance formularies through the end of the calendar year as long as they submit prior e-mail notification to CMS at PartDFormularies@cms.hhs.gov to document the changes.

Formulary Timeline – CY2007 and CY2008 Updates



II. August Limited Update Window for CY 2008 Formulary Submissions

Part D sponsors will have the opportunity to make updates meeting certain criteria to their conditionally approved CY 2008 formulary submissions from 12:00 AM EDT August 8, 2007 through 11:59 PM EDT August 10, 2007. This will be the only opportunity to make changes to the CY 2008 formulary submission prior to March 1, 2008. Only formularies that have received prior conditional CMS approval will be permitted to submit an update during this period.

Assuming a plan has a formulary with conditional approval, this 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 formularies 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 be considered the final CY 2008 formulary submission. No exceptions will be granted and, therefore, we strongly encourage Part D sponsors to perform sufficient quality assurance checks prior to

submitting to CMS. Allowable and Non-Allowable changes to CY 2008 formulary submissions during the August Limited Update Window are shown in Attachment 1.

In order to facilitate the review, all offsetting changes (both Brand/Generic and Therapeutic Substitutions) must be identified in the attached "Offsetting Changes" 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 "Offsetting Changes" 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 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 submission may result in rejection of the submission.

Following the update window, Part D sponsors will need to check the status of formulary approvals in HPMS. Only approved formularies may be marketed beginning October 1, 2008. 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 on CY 2007 Negative Formulary Change Requests or the August Limited Update Window for CY 2008 Formulary Submissions, please contact Kady Flannery (kathleen.flannery@cms.hhs.gov or 410-786-6722), Rebecca Decastro (Rebecca.decastro@cms.hhs.gov or 410-786-4036), or Lorelei Piantedosi (lorelei.piantedosi@cms.hhs.gov or 410-786-8651).

Attachment 1.

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

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 more favorable beneficiary cost-sharing 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 v3.0 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 July update to the CY 2008 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 number 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 supply of drugs currently existing on the conditionally approved initial formulary submission

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 less favorable beneficiary cost-sharing, unrelated to offsetting Brand/Generic or Therapeutic Substitutions or FRF deletions, as described above

5. Changes to the CY 2008 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 "Offsetting Changes" Template

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 2008 formulary ID (preceding zeros should be omitted). **Only one formulary ID may be entered per field and per template**.
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 2008 FRF. This code should not contain dashes, spaces or other characters.
4. Affected Brand Name, Generic Name, Dosage Form 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 2008 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 2008 FRF Proxy Code, Brand Name, Generic Name, Dosage Form, 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 8, 2007 and 11:59 PM EDT on August 10, 2007. 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: **CY08OffsetTemplate_IDxxxx**. The four digit ID number should reflect the formulary ID for which changes are being requested. Only the information found in the Offsetting Change Template will be considered in the review of your resubmission and any altered or recreated templates may be rejected.