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

CENTER FOR BENEFICIARY CHOICES

Date: December 15, 2006

To: All Part D Sponsors

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

Subject: CY 2007 Formulary Changes – New December Enhancement Window and CY 2007 Formulary Update Guidance

This document outlines operational details regarding a CY 2007 December Formulary Enhancement window, and the revised process for submitting negative change requests and monthly formulary updates throughout CY 2007. The *Formulary Changes During the Plan Year* policy released in April 2006 (http://www.cms.hhs.gov/PrescriptionDrugCov Contra/ Downloads/MemoFormularyChangeGuidance_04.27.06.pdf) provides detailed guidance on how CMS views negative formulary changes. For CY 2007 CMS requires prior notification of formulary enhancements as described in question one below.

CY 2007 Formulary Enhancement Open Period – December 2006

CMS recognizes that some Part D plan sponsors continue to broaden their coverage of Part D drugs and may wish to reflect this coverage in the Medicare Prescription Drug Plan Finder (MPDPF) tool prior to the March 2007 release. It is for this reason that CMS is offering another formulary enhancement submission window between 12:00AM EST on December 18, 2006 through 11:59PM EST on December 27, 2006. Please note that there is not a scheduled update of the Formulary Reference NDC File that coincides with the availability of this submission window. The Formulary Reference NDC File will be updated prior to the February 2007 monthly update window.

The December open period is for formulary enhancements and removal of non-Part D drugs only. CMS is defining formulary enhancements as strictly the following sorts of changes:

1. The addition of a new Part D drug to the formulary file
2. The reduction in cost-sharing level for a Part D drug
3. The removal of prior authorization or step therapy requirements for a Part D drug
4. The removal of quantity limit restrictions on a Part D drug. In addition, an increase in the quantity limit amount or a decrease in the quantity limit days, without changes to the other variable would also be considered enhancements.

In addition to formulary enhancements, Part D plan sponsors should take this opportunity to remove any non-Part D drugs that may have been inadvertently included on their formulary files. For example, in response to the FDA's recent public notice regarding quinine (http://www.fda.gov/bbs/topics/NEWS/2006/NEW01521.html), all unapproved quinine products should be removed from all formulary files that may contain them. When removing unapproved drug products during the December open period, please provide CMS notification of the removal via the negative formulary change template addressed in this guidance document. Please note that the negative formulary change template has been revised, and that only this revised format may be submitted (see details below.)

ALERT – Similar to the October enhancement window, if changes other than those outlined above are included on the formulary files submitted between December 18 and December 27, these files will be denied, and plan formularies will revert to the same last approved formulary as of December 17, 2006. Please also be reminded that the MPDPF pricing file submission for January 16, 2007 should contain pricing information for all drugs on the approved formulary as of 11:59 PM EST on January 11, 2007. If subsequent MPDPF update files submitted to Destination Rx do not match the most recent approved formulary file, pricing information may be suppressed in MPDPF.

Please ensure that these instructions are followed to prevent update failures and MPDPF suppression. If you have any questions about these files, please contact Brian Martin at (410) 786-1070 or Rebecca Decastro at (410) 786-4036.

CY 2007 Formulary Update Processes

(The process below is for formulary changes in CY 2007)

Requesting CY 2007 Formulary Changes

The process for requesting and implementing formulary changes for CY 2007 are addressed below. CMS will continue to require prior notice of formulary enhancements. For negative formulary change requests, Part D plan sponsors will generally follow the same process as that for CY 2006 formularies with any exceptions noted below. Part D plan sponsors should make every effort to precisely follow these instructions, as failure to do so may result in formulary denial and a delay in the implementation of formulary changes.

Q1: What is the process for enhancing the formulary such as adding new drugs, improving the cost-sharing status of a drug, or removing utilization management restrictions after January 1, 2007?

A1: We have previously described the process for enhancing CY 2007 formularies prior to the February 2007 open submission window (http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MemoFormularyEnhancements_10.05.06.pdf). CMS will continue to require prior notification of formulary enhancements for CY 2007 and subsequent plan years. For any formulary enhancements that will be implemented prior to the effective date of an HPMS formulary submission

reflecting such enhancements, plan sponsors should follow the process as noted in the above guidance. For instance, if drug A will be covered starting on March 1, 2007, and drug A is included on the February HPMS formulary file submission, CMS considers the formulary upload to be prior notification, assuming that the February HPMS submission has a March effective date. However, if formulary coverage of drug A will begin on February 14, 2007, the plan sponsor must notify CMS of the enhancement prior to February 14, 2007. In addition, drug A should be included in the HPMS formulary submission during the March open period.

Q2: What is the process for making a negative formulary change such as removing a drug from the formulary, changing the cost-sharing status of a drug to a less favorable position, or adding utilization management restrictions?

A2: CMS' negative formulary change policy has been previously detailed in the *Formulary Changes During the Plan Year* policy released in April 2006 (http://www.cms.hhs.gov/PrescriptionDrugCov Contra/ Downloads/MemoFormularyChangeGuidance_04.27.06.pdf). Plan sponsors should submit their proposed changes via the attached CY 2007 Negative Formulary Change Notification Template at least 60-days prior to the effective date of the change. If approved, the proposed change should then be submitted as part of the monthly formulary updates in the month preceding the proposed effective date. For example, if a drug will be removed from the formulary on May 1, 2007, then the proposed negative change template should be sent to CMS on or before March 1, 2007. If approved by CMS, the proposed negative change should be reflected in the formulary update submitted as part of the formulary flat file submitted in April 2007.

Q3: What is the process for adding a new generic drug and changing the status of the corresponding brand drug (e.g. deleting the drug or moving it to a higher cost-sharing tier)?

A3: CMS should be notified of all formulary additions prior to the effective date consistent with the process outlined above. Any corresponding negative change to the brand drug is subject to the 60-day notice rule. Additionally, the utilization management requirements imposed upon the new generic can not be more restrictive than that of the corresponding brand drug. Plan sponsors should submit their proposed change via the Negative Formulary Change Notification Template at least 60-days prior to the effective date of the change. If approved, the proposed change should then be reflected in the formulary update submitted in the month preceding the proposed effective date. For example, if the brand drug will be removed from the formulary on May 1, 2007, then the proposed negative change template should be sent to CMS on or before March 1, 2007. The proposed negative change would be submitted as part of the formulary flat file in April 2007.

Q4: How should the Negative Formulary Change Notification Template be completed?

A4: The Negative Change Template for CY 2007 must be used for submitting negative change requests. This template is similar in format and design to the one used for CY 2006 with some modifications. **Change requests submitted using the old CY 2006 template will not be considered by CMS.** Most fields of the new template are free text; however, for those fields with a drop-down menu, a selection must be made from the existing options. Once a type of change is selected there will be a series of blank and/or pre-populated cells following this field. Cells pre-populated with "NA" do not require additional data entry; however, each blank or required cell following the type of change designation must be completed prior to submission to CMS. Negative change requests with blank required fields will not be accepted and may delay the review process of any remaining requests.

Similar to CY 2006, only one formulary ID and one drug's information should be entered per cell. Changes that apply to multiple formulary IDs and/or more than one drug (affected or offset) must be entered on separate rows. In addition, only valid CY 2007 formulary IDs should be entered in the Formulary ID column. **Use of invalid IDs (e.g. CY 2006 IDs, Contract IDs, or other non CY 2007 IDs) may result in a delayed review of the template and/or denial of the request(s).**

In accordance with our guidance the effective date entered in column 2 must be at least 60 days from the date of the negative change request. Failure to comply with this policy may result in the denial of the request.

All information pertinent to the "Affected Drug" and "Offset Drug" fields (proxy code, brand name, generic name, dosage form, and strength) should be copied directly from the Formulary Reference NDC file. Use of alternative descriptors or typos incurred from manual entry into these fields may delay the review of the requested changes.

The justification field must be completed if blank and should provide concise information that is sufficient to justify the type of change requested. Pertinent information such as data source (e.g. FDA, manufacturer), date/reason for market removal, rationale for non-Part D status (e.g. DESI LTE (#)), criteria for B versus D consideration (e.g. antiemetics), brief FDA warning or clinical guideline summaries, and therapeutic exchange data (e.g. proxy code, brand name, etc) should be included as applicable. Failure to provide appropriate or incomplete justifications may result in a delayed review or denial of the request(s).

Q5: How should the Negative Formulary Change Notification Template be submitted to CMS?

A5: The CY 2007 Negative Formulary Change Notification Template should be submitted to the Part D mailbox (PartDformularies@cms.hhs.gov) at least 60 days prior to the anticipated implementation date of the negative change(s). This worksheet should be copied or forwarded in its entirety to maintain formatting integrity. The subject line of

the email submission, as well as name of the Negative Change Template (NCT), should use the following format: NCT_mmddyy_IDxxxx. The date-in-naming convention should reflect the template submission date, and the four digit ID number should reflect the formulary ID for which changes are being requested.
If change requests are included for multiple formulary IDs on a single template, please separate ID numbers in the subject line and document name by an underscore (e.g. NCT_020307_ID7998_7999).

Please only provide contact information in the body of the email.

Q6: What is the process for removing a drug from our formulary when the drug is being withdrawn from the market due to safety reasons?

A6: In this instance, plan sponsors are not required to provide CMS with written notice that the drug is being removed from the formulary, but should instead remove the drug immediately. The HPMS formulary flat file should then be updated during the first available monthly update period to reflect such a change. If formulary deletion of the affected drug results in a particular category or class containing only one drug, a second drug must be added to the formulary to offset the deletion (if another drug in that class exists).

Q7: Will plan sponsors receive written approval of their 60-day notice changes?

A7: Plan sponsors will receive written approval of their negative change requests for all types of negative formulary change requests. Formulary maintenance changes may be considered approved if plan sponsors do not hear from CMS within 30 days of change request submission. However, "Other Formulary Changes" must not be implemented until explicit notification of approval is sent by CMS and all other 60 days notice requirements are met.

Monthly Formulary Update Formulary File Submissions

The following questions and answers provide operational guidance for submitting HPMS formulary files during CY 2007. Because the use of the Formulary Reference NDC File has streamlined the formulary submission process, the open periods for CY 2007 are narrower than for CY 2006 formularies. In addition, in an effort to coordinate formulary submissions and approvals with price file submissions and MPDPF posting dates, the open formulary submission periods will now be limited to the first three business days of the month. The attached calendar contains formulary and price file submission dates, as well as MPDPF posting dates.

Q8: Are plan sponsors required to submit a formulary file each month to HPMS for review and approval?

A8: Plan sponsors are only required to submit a formulary file to HPMS when changes such as enhancements or negative changes previously submitted to and approved by CMS, are to be incorporated into the files.

Q9: How often may Part D sponsors update their HPMS formulary flat files?

A9: Part D sponsors may update their HPMS formulary flat files once a month, beginning in February 2007 for an effective date as early as March 1, 2007. Updated formulary flat files should be submitted one month prior to the intended effective date and should always contain the complete formulary file, not just the formulary changes. Formularies that are not uploaded and successfully validated during the stated open period will be denied.

Q10: When uploading my monthly formulary update, what option in HPMS do I choose?

A10: When uploading monthly formulary changes, plan sponsors should use the "Update" option in HPMS to send their complete formulary file and attachments.

Q11: Do plan sponsors need to complete the effective date field when uploading monthly formulary changes to HPMS?

A11: A formulary effective date must be associated with each formulary update. A future date may be entered; otherwise this date will default to the first day of the following month.

Q12: Can I submit negative changes to my HPMS formulary file without prior CMS approval of the changes?

A12: No. Only those negative changes that were previously approved by CMS, as well as any drugs withdrawn from the market for safety reasons, may be submitted with the HPMS formulary upload. **If there are additional negative changes submitted that did not receive prior approval, the entire HPMS formulary file will be denied.** The formulary may not then be resubmitted until the following month's open submission period. Any negative changes contained within the denied file will not be reflected in the MPDPF and may not be implemented or marketed. If the denied HPMS formulary submission contained enhancements, the plan sponsor must notify CMS of such enhancements using the formulary enhancement template. These enhancements may still be marketed and implemented, but will not appear in MPDPF due to the denial of the formulary submission. These enhancements should be included in the subsequent month's formulary upload.

Q13: Are we required to resubmit our prior authorization and step therapy attachments with each formulary upload?

A13: Plan sponsors are required to submit their prior authorization and step therapy attachments with each HPMS submission, unless there are no changes in the drugs that require such edits. These documents must be updated accordingly to reflect any changes in drug therapy coverage. For instance, if a newly approved drug is added to the formulary file with prior authorization requirements, the prior authorization criteria for this new drug must be included with the submission that contains the drug. Similarly, if prior authorization requirements are removed during an upload, the criteria for this drug

should also be removed from the prior authorization file. If there are no changes in the prior authorization and step therapy attachments, the previously uploaded versions may be used.

Q14: Will plan sponsors be notified when their formularies are approved?

A14: No. The status of your submitted formulary (approved or denied) may be viewed in HPMS through the Formulary Status History Report.

Q15: How should plan sponsors coordinate formulary submissions and MPDPF pricing file submissions?

A15: Plan sponsors are reminded that MPDPF pricing files must contain pricing for all drugs included in their current CMS-approved formulary. Since formulary submission dates and MPDPF pricing file submission dates differ, it is imperative that plan sponsors continuously refer to the attached calendar to ensure the coordination of formulary and pricing updates. For example, formulary updates submitted between February 1 and February 3, 2007 will be reviewed for approval by February 19, 2007. Plan sponsors should prepare MPDPF pricing files to include pricing information reflecting these formulary changes for submission to DestinationRx on February 27, 2007. If the submitted formulary file is not approved by 11:59 PM Eastern Time on February 19, 2007, plan sponsors should submit MPDPF pricing files reflective of the previously approved formulary.

Q16: Can monthly updates for CY 2007 formulary be automatically added to the corresponding CY 2008 formulary?

A16: No. The CY 2007 and CY 2008 formulary files must be maintained separately.