

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR BENEFICIARY CHOICES

Date: October 5, 2006

To: All Part D Sponsors

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

Subject: CY 2006 and CY 2007 Formulary Changes – New October Submission Window and Policy on Enhancements Added Between the October and February Submissions

CMS views formulary enhancements favorably and recognizes that broader access to Part D drugs is valuable for Medicare Part D beneficiaries. When making enrollment decisions, CMS also understands the importance for beneficiaries in having the most accurate and up-to-date formulary coverage information available in the Medicare Prescription Drug Plan Finder. However, it is critical for CMS to maintain the integrity of and consistency between the approved HPMS formulary files and the information that is displayed in the Medicare Prescription Drug Plan Finder (MPDPF). While the revised formulary submission process for CY 2007 has ensured this synchronization and the display of only CMS approved formulary information, we do understand that it has limited the flexibility of changes to the formularies and MPDPF uploads in comparison to the CY 2006 plan year processes.

The initial release of MPDPF scheduled for October 12, 2006 will be based on the last approved formulary files as of October 2, 2006. (The most recent window for selected formulary changes closed September 19th, so plan formularies in MPDPF as of October 12, 2006 will either reflect the formulary file with the selected changes approved at that time or the previous approved formulary file submitted.)

Since only approved HPMS formulary files will be displayed in the Medicare Prescription Drug Plan Finder for CY 2007, CMS has made arrangements to offer Part D plan sponsors one additional opportunity to enhance formularies prior to the beginning of the coordinated election period. This open October submission period is for **formulary enhancements only** and will be available from 12:00AM EDT on October 9, 2006 through 11:59PM EDT on October 13, 2006.

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-share 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.

Once approved, these enhanced formulary files will be included in the November 15, 2006 release of Medicare Prescription Drug Plan Finder. Other types of changes, including maintenance changes, to CY 2007 formularies may not be made effective until 60 days after the beginning of the contract year, in accordance with our *Formulary Changes During the Plan Year* policy. This ensures a stable basis for plan comparisons in MPDPF throughout the open enrollment period.

ALERT - If changes other than those we have designated as enhancements are included on the formulary files submitted between October 9 and October 13, these files will not be approved, and plan formularies will revert to the same last approved formulary as of October 2, 2006. Please also be reminded that if subsequent MPDPF update files submitted to Destination Rx do not match the most recent approved formulary file, plan information may be suppressed in MPDPF.

Despite the limited opportunities to update the formularies displayed in MPDPF, CMS understands that Part D plan sponsors may wish to add and market additional formulary enhancements between October 13, 2006 and the next opportunity for formulary submissions on February 1 – 7, 2007. As a result, CMS will allow sponsors to make further enhancements (again, exclusively positive changes) to formularies during this period without formal submission to and approval by CMS, as long as (1) plans send us an e-mail notification as described below and (2) these enhancements are included in the February 2007 HPMS formulary submissions. This means that such enhancements may be offered by plans and included on plan websites and in any printed formulary materials, but will not appear in MPDPF during the open enrollment period and until submitted and approved during the February HPMS open formulary submission window.

Prior to making any such further enhancements, plans must send e-mail notification to PartDFormularies@cms.hhs.gov to document the changes. The subject line of the e-mail should be limited to “Enhancement to CY 2007 Formulary”. Plans must ensure they provide the formulary IDs and the proxy NDC code, brand name, generic name, dosage form, and strength using the attached Excel file template. These fields should be populated using the Formulary Reference NDC File. For new Part D drugs that are not yet included on the Formulary Reference NDC File, an example proxy NDC should be submitted and the naming convention should match that of the reference file. For those drugs that will be added to the formulary on a specialty tier, the cost criteria utilized to determine qualification for specialty tier placement should also be included on this

document. CMS will use these notifications to reconcile with the formulary update files submitted in February 2007.

The Frequently Asked Questions listed below provide operational details for making formulary enhancements to the CY 2007 formularies.

CY 2007 Formulary Enhancements

Q: When can Part D plan sponsors submit an updated formulary file with enhancements?

A: The window to submit formulary enhancements will be from 12:00AM EDT on October 9, 2006 through 11:59PM EDT on October 13, 2006. All submitted formularies must pass validation during this open period. Any formulary that does not validate prior to the conclusion of the open period will be denied. Plan sponsors should also ensure that the submitted formulary files are accurate, as there will not be an opportunity to resubmit the files once successfully validated.

Q: Which files should be submitted to HPMS during this open period?

A: The updated formulary submission should contain the most recently approved HPMS formulary file along with any applicable formulary enhancements. In addition, complete prior authorization and step therapy supporting files should also be included with the formulary upload.

Q: How do these formulary enhancements differ from formulary maintenance changes that are outlined in the *Formulary Changes During the Plan Year* policy?

A: Formulary maintenance changes are negative formulary changes. Although these are negative changes that CMS generally approves, they still result in an overall negative change to the formulary. As such, formulary maintenance changes such as the deletion or tier increase of a brand drug with a corresponding addition of an equivalent generic are not permitted during this open period. If negative changes are included during this October submission, the formulary will be denied.

Q: Can a drug be added to the formulary file with utilization management restrictions?

A: If a drug is not contained on the most recently approved formulary, it may be added with utilization management restrictions. For those drugs that are added to the formulary that require utilization management, the appropriate formulary supporting document must be updated to reflect this addition. Prior authorization,

step therapy, and quantity limit restrictions should be consistent with FDA-approved labeling.

Q: How can Part D plan sponsors check on the status of their formulary submissions?

A: CMS will review all submitted HPMS formulary files prior to the November 2, 2006 data pull for the November 15, 2006 release of the Medicare Prescription Drug Plan Finder. As with the previous CY 2007 formulary update periods, CMS will not provide explicit notification of formulary approval. Part D plan sponsors should utilize the formulary status history report function in HPMS to view the status of their formulary submissions.

Q: What happens if my formulary submission is denied?

A: CMS will deny formulary submissions that contain any change not listed as an enhancement above. The November 15, 2006 Medicare Prescription Drug Plan Finder will only display the most recently approved formulary files. As such, any intended enhancements submitted in the formulary file submission will not be displayed in the Medicare Prescription Drug Plan Finder.

Q: Will there be another opportunity to submit formulary enhancements to HPMS prior to January 1, 2007?

A: No. This open period is the last planned formulary update period prior to the February 2007 open submission window.

Reminder: 2006 Formulary Changes

CMS would also like to remind Part D plan sponsors that October 7, 2006 is the final date that negative change requests may be submitted for CY 2006 formularies. Similarly, the last opportunity to submit updated CY 2006 formulary files to CMS for review is during the November 1-7, 2006 open period. These dates are necessary to allow for CMS review of negative change requests and the corresponding formulary submissions.

If you have any questions regarding this update period, please contact Brian Martin (brian.martin@cms.hhs.gov) or Rebecca Decastro (rebecca.decastro@cms.hhs.gov).