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

CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

Date: August 4, 2006

To: All Part D Sponsors

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

Subject: August Update Window for CY 2007 Formulary Submissions

The open period to update CY 2007 formulary submissions will be August 1, 2006 to August 25, 2006. During this open period, conditionally approved initial formulary submissions may be updated as outlined in the FAQs below. For those formularies that have not yet received conditional approval, there will be an opportunity to submit a formulary update once the approval is granted. Every effort should be made to limit formulary changes to those addressed in the FAQs, as commencement of marketing may be delayed as a result of additional formulary changes during the August open period.

Frequently Asked Questions – August Open Period

Q: Will there be an opportunity to update formularies prior to January 1, 2007?

A: Organizations will be permitted to update conditionally approved formularies from August 1, 2006 through 5:00pm EDT August 25, 2006 (open period). This window will provide the last opportunity to incorporate updates into the formulary until 60-days after the beginning of the contract year. Each formulary may be uploaded once during the aforementioned window. HPMS will not allow multiple uploads during the open period. CMS will begin reviewing formularies on a rolling basis as they are received during this time period, so we encourage you to submit as early as possible. If an initial April formulary submission is granted conditional approval after August 1, 2006, there will be an opportunity to submit an updated file during this open period.

Q: What types of formulary changes will be permitted during the August open period?

A: CMS expects organizations to only make minor adjustments to the conditionally approved formularies, such as adding new drugs or enhancing the formulary in other ways. Any negative changes to the conditionally approved formularies should be limited to "Formulary Maintenance Changes", as described in the *Formulary Changes During the Plan Year* policy document. These would include the following:

1. Removal or placement in less preferred tier of a brand drug upon the availability and addition of an A-rated generic or multi-source brand equivalent, at a lower tier or cost to the beneficiary.

2. Removal of a drug based upon a new FDA "black box" warning or market withdrawal.

3. Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS (e.g. CDC's recommendation against using older antivirals for treatment and prophylaxis of the flu)

4. The addition of utilization management when necessary to effectuate other acceptable formulary changes (e.g. prior authorization on a brand drug when generic is now available on formulary at a lower cost), to help determine B vs. D coverage (subject to CMS guidance on least burdensome ways to make this determination), or to promote safe utilization of a Part D drug based upon new clinical guidelines or information.

In addition to these "Formulary Maintenance Changes", minimal substitutions within classes are also permitted (e.g. adding a brand Proton Pump Inhibitor and removing a different brand Proton Pump Inhibitor). However, the drug that is added to the formulary should be at the same cost share and contain the same type of utilization management edits as the drug that it is replacing. Aside from the examples outlined above, new utilization management restrictions will be limited to drugs that are added to the formulary during the August submission. It is our expectation that there will not be any other types of negative changes to the formulary, both in regard to the drug list (removal of drugs without substitution within the same class or category), as well as the addition of utilization management tools. These changes could potentially jeopardize the conditionally approved status and lead to non-approval of your formulary. Plans may not change their categorization systems at this time (e.g. switching from USP to an alternative categorization system).

Q: How do we submit a formulary update to HPMS?

A: When accessing HPMS to update a formulary, the Formulary Revision option should be selected. Once the user is in the Formulary Revision screen, the Updates section should be utilized. A prior authorization attachment and a step therapy attachment must be uploaded if the formulary contains such requirements.

Q: How will this formulary update affect our marketing?

A: CMS understands the proximity of this review to the marketing activities commencing on October 1, 2006. Therefore, CMS will make a profound effort to review all updates to submitted formularies prior to October 1, 2006. Please note that the Medicare Prescription Drug Plan Finder will only display the last approved formulary file. As such, organizations should make every effort to limit the scope of changes to allow for formulary approval prior to the September 26, 2006 data submission. The next available Medicare Prescription Drug Plan Finder data submission and release will be November 2, 2006, and November 15, 2006, respectively.

Q: Will we receive a communication from CMS that our formulary has been approved?

A: Organizations may check the status of formulary approvals in HPMS. Marketing of your formulary should not begin before approval of the submitted updates has been granted. If you choose not to submit updates, you may proceed with marketing of your formulary on October 1, 2006.

Any questions regarding the August open period should be directed to Brian Martin (brian.martin@cms.hhs.gov) or Aaron Eaton (aaron.eaton@cms.hhs.gov).