



Center for Beneficiary Choices

---

MEMORANDUM

TO: All Part D Plan Sponsors

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

RE: Supplemental Drug File Submission, Drugs Subject to Limited Distribution and Prior Authorization for Excluded Drugs

DATE: April 11, 2008

This memo addresses a number of technical issues related to both the CY2008 and CY2009 formulary and supplemental drug file submissions.

**CY2008 Supplemental Drug File Submissions**

The following information is provided to clarify the process for submitting supplemental formulary files for plans offering gap coverage for a subset of any tier and/or free first fill (FFF) as part of their benefit design. Updates to these files can only be done during the formulary submission window as stated on the Formulary Guidance section of [www.cms.hhs.gov](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MPDPFDataRequirementsSubmissionGuidelines_NextYear.pdf) ([http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MPDPFDataRequirementsSubmissionGuidelines\\_NextYear.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MPDPFDataRequirementsSubmissionGuidelines_NextYear.pdf)).

When submitting a monthly formulary update, plans are given a choice to use the last supplemental file submitted or upload a new file. CMS expects that a new file upload would only be necessary if there were approved changes to the current formulary file that would also affect this file.

If a new supplemental file is uploaded and the plan removes drugs from the supplemental file that were not approved by CMS, these deletions constitute negative changes. The modified supplemental file would result in inaccurate benefit information being displayed on the Medicare Prescription Drug Plan Finder (MPDPF) that may be misleading to the beneficiary. As a result the plan will be suppressed on the MPDPF until an updated supplemental file is uploaded and reviewed to ensure all errors have been corrected. The corrected supplemental file must be uploaded during the next formulary submission window.

If the plan indicates that a new file is to be uploaded but then does not upload a file, there will also be an error. This would result in no displayable supplemental file for the plan since there would

not be a supplemental file associated with the new formulary being submitted. This error would result in plan suppression on the MPDFP.

If the plan elects to use the previously submitted supplemental file, it must make sure that drugs on this supplemental file remain consistent with its associated submitted formulary. If any NDCs listed on the supplemental file have been removed from the formulary, the plan would not be able to use the previously submitted supplemental file. The plan must delete these drugs from the supplemental file and upload the new supplemental file during the formulary submission window.

### **CY 2009 Formulary and Supplemental Drug File Submissions**

For CY 2009 plans, in addition to gap coverage and FFF supplemental files, some plans, depending on the benefit design, may also need to submit supplemental files for excluded drugs, over-the-counter (OTC) medications and home infusion medications bundled under Medicare Part C. The submission gates may be open as early as June 3. All of these supplemental files should be submitted by **11:59 PM PDT June 9, 2008**. Since many of these files are new files for CY 2009, CMS will allow a window to accommodate any technical issues that may arise with a plan's initial submission. This window will close June 12, 2008.

#### Drugs Subject to Limited Distribution

For each drug on the submitted formulary flat file there is a flag indicating whether the particular drug is subject to limited distribution through certain pharmacies only. Once the formulary is approved, this indicator can not be changed from 0 (No) to 1 (Yes) with subsequent formulary submissions without prior notification and approval by CMS. Changing this indicator to require limited distribution would only be permitted if there were a change in FDA policy restricting the drug to distribution only by specific pharmacies. Unauthorized changes from a 0 to 1 in the CY2009 formulary limited distribution field may result in compliance actions.

#### Prior Authorization: Excluded Drugs

Please note that if an Enhanced Alternative plan indicates prior authorization (PA) for any drugs on their Excluded Drug supplemental formulary file, the associated PA criteria, if approved, must be available on their Part D plan's formulary website for display on November 15, 2008. The plans would be expected to display all of the PA criteria contained within the approved PA file without modification.