DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Beneficiary Choices

MEMORANDUM

To: All Part D Plans

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

Subject: Mid-Year Formulary Reference File Proxy NDC Changes

Date: June 1, 2007

We have received a number of Part D Sponsor inquiries regarding the mid-year removal of a formulary reference file (FRF) proxy national drug code (NDC). These questions have ranged from what does a FRF proxy NDC represent to how should a Part D Sponsor react to the mid-year removal of a proxy NDC. To address these and other related questions we have provided additional information on the Formulary Reference File and proxy NDCs.

If you have any questions please contact:

- Kady Flannery on issues relating to the formulary reference file at Kathleen.Flannery@cms.hhs.gov or 410-786-6722.
- Greg Dill on issues relating to formulary policy and the criteria of a Part D drug at Gregory.Dill@cms.hhs.gov or 312-353-1754.
- Merri-Ellen James on issues relating to PDE Submission at Merri-Ellen.James@cms.hhs.gov or 410-786-4462.

Question: What is the Formulary Reference File (FRF)?

Response:
As we discussed in our March 1, 2006 memorandum, the FRF is a list of drug products represented by proxy national drug codes (NDCs) that CMS has identified for the purpose of streamlining the formulary submission process and the synchronization of HPMS formulary files and MPDPF formulary display (see http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/FAQCY07FormRefNDCFile 03.01.06.pdf). Proxy NDCs can represent multiple NDCs for similar drug products with the same active ingredient, dosage form, strength and route of administration. Use of a proxy NDC in the FRF reflects CMS' current understanding that one or more drug products with NDCs represented by the proxy NDC can satisfy criteria necessary to be considered a Part D drug; however, it does not represent a coverage determination that any specific drug product is a part D drug. Part D sponsors continue to be ultimately responsible for making coverage determinations and should not necessarily cover or exclude from coverage a drug product based solely on the presence or absence of a proxy NDC on the FRF.

Question: What is the impact of a mid-year deletion of a proxy NDC from the 2007 CMS Formulary Reference File (FRF) on the submission of prescription drug events?

Response: Part D sponsors should remove all deleted FRF proxy codes from their HPMS formulary files and all drug products represented by the deleted proxy codes from their adjudication files unless CMS indicates that the FRF proxy deletion is not based upon a change in Part D status. For any questions regarding specific drug product approval status, we encourage Part D sponsors to contact the Office of Compliance at the Food and Drug Administration (FDA) at 1888-INFO-FDA, 301-827-4570 or http://www.fda.gov/cder/comment.htm.

CMS has established edits to exclude prescription drug events (PDEs) from being accepted for any NDCs represented by the deleted proxy, as applicable. Beginning with the May 24, 2007 FRF update, the effective date for Part D sponsor implementation of these changes with regard to PDE submissions of NDCs associated with deletions from the FRF is ninety days following the FRF updated posting in the formulary submission module of HPMS. For example, if CMS provided notice of a proxy NDC deletion on May 24, 2007 based upon a new LTE DESI determination by FDA, a Part D Sponsor would have until August 22, 2007 to remove the implicated drug product(s) (and any applicable NDCs) from their adjudication files. While claims with dates of service through August 22, 2007 will be available for PDE submission, PDEs will no longer be accepted for the LTE DESI product for claims with dates of service after August 22, 2007.

The prospective PDE effective date of CMS' determination means that Part D Sponsors will not be required to retrospectively adjust PDEs, a beneficiary's true out-of-pocket costs, or total drug spend as long as changes are promptly addressed. CMS expects Part D plans to provide affected beneficiaries with 60 days advanced notification of the associated negative formulary changes. As of the effective date of the prospective PDE change, any non-Part D drugs must be removed from formularies and should no longer be available for Part D reimbursement. Plan sponsors are not required to submit negative change requests for FRF deletions of non-Part D drugs.

For deletions from the FRF that occurred in January, February, and March of this year, CMS has established June 1, 2007 as the effective date. Therefore, Part D sponsors should not submit PDEs for claims with dates of service after May 31, 2007 for drug products represented by the deleted proxy codes. Exceptions to this prospective June 1, 2007 effective date include: 1) proxy code deletions listed in appendix A that were unrelated to a change in Part D status; 2) unapproved quinine products, effective date of January 1, 2007 (see http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY07FormularyChanges.pdf); and 3) DESI LTE drugs listed in Appendix 1 of the December 5, 2006 memo for which a transition supply was allowed through January 31, 2007 (see http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/QADESICancer_12.05.06.pdf).