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

CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

Date: February 27, 2007

To: All Part D Sponsors

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

Subject: CORRECTED February Update of the Formulary Reference NDC File for CY 2007 Formulary Submissions

The Formulary Reference NDC File (FRF) has been updated to include additional Part D covered drugs and remove non Part D or excluded drugs. The changes reflected in this update will be effective March 1, 2007 with regard to formulary flat file submissions. Prior to uploading during the March open window period, Part D sponsors should modify flat files accordingly to include only those NDCs contained in this FRF version. For Plan Finder pricing submissions, Part D sponsors should use the last approved version of their formulary and the most current Formulary Reference NDC File. Please note that the Formulary Reference File is not intended to be a comprehensive listing of Part D eligible drugs and it is ultimately the responsibility of the organizations to make drug coverage determinations (Part D or otherwise), regardless of whether they appear on this file.

The Formulary Reference File Change Report contains a list of drug record changes since the last Reference File posting on January 23, 2007. The types of changes found in this version of the FRF change Report are as follows:

- Addition - Identifies a new record on the Formulary Reference NDC File. This record may represent a new drug (brand or generic) or other Part D covered drug not present in a previous version of the file.
- Deletion - Identifies a record that has been removed from the Formulary Reference NDC File. This record may represent a discontinued, withdrawn, excluded or otherwise non-Part D covered drug. Drugs deleted from the FRF will not pass validation and therefore must be removed from flat files prior to uploading during an open window period.

Deletions from this version of the Formulary Reference File concern the removal of non Part D covered drugs including:

- DESI LTE drugs (e.g. chloroxylenol/hydrocortisone/pramoxine hydrochloride combination products, guaifenesin/phenylephrine/pseudoephedrine combination products)

- drugs without an approved FDA application (e.g. digoxin 0.5mg tablets, select dyphylline products, dyphylline/guaifenesin combination products, hydrocortisone acetate/lidocaine hydrochloride combination products)
- drugs not listed as RX with the FDA (e.g. stannous fluoride 0.4%, select diphenhydramine products, Motrin® 100mg/5ml)

Non Part D drugs deleted from the FRF may be removed from coverage effective immediately without submission of a negative change request to CMS. Notification to all other interested parties regarding discontinued coverage of these drugs is encouraged.

The updated Formulary Reference NDC File and Formulary Reference File Change Report will be available for download (5) business days prior to each CY2007 open window period. These files will be posted within the Formulary Module in HPMS and on the following link: (http://cms.hhs.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp). For your convenience, an updated NDC Crosswalk File will also be available for download within the HPMS Formulary Module. This file provides a sample list of NDCs that can be linked to the Proxy NDC Codes. These linked NDCs are intended to be used only as a guide for drug identification and should not be used to create the formulary files submitted in HPMS.

Any questions regarding the Formulary Reference NDC File should be directed to Judy Geisler (judith.geisler@cms.hhs.gov) or Kady Flannery (kathleen.flannery@cms.hhs.gov). Any questions regarding pricing file submissions should be directed to Stacy Matheny (stacy.matheny@cms.hhs.gov).