

Formulary Reference NDC File

For CY 2006, organizations are required to create and maintain separate formulary files for the purposes of the HPMS formulary review and for display on the Medicare Prescription Drug Plan Finder (MPDPF). These files have considerable differences, thus creating additional burden to both organizations and CMS in terms of maintenance and review. In an effort to streamline this process and minimize redundancy for CY 2007, a new process involving the use of a Formulary Reference NDC File has been developed that will facilitate the use of one formulary file for all requirements.

Question 1

Q: What is the Formulary Reference NDC File?

A: The Formulary Reference NDC File is a file created and maintained by CMS that contains a list of drugs that may be included on Part D formularies. Each row of the file represents a single drug identified by a proxy NDC code, brand name, generic name, dosage form, and strength. Organizations should note that the NDC used on the Formulary Reference NDC File only serves as a unique identifier for a drug, similar to a randomly assigned code. It is not intended to endorse or otherwise encourage the use of a particular manufacturer.

Question 2

Q: Why did CMS create the new Formulary Reference NDC File process?

A: The Formulary Reference NDC File process was created in order to streamline the HPMS formulary upload, validation, and review processes as well as the data submission process for the Medicare Prescription Drug Plan Finder (MPDPF). We have received industry commentary, both informally and formally through our “Lessons Learned” feedback, indicating that organizations would prefer one formulary file format for both HPMS and MPDPF. Organizations have also expressed concerns regarding the problems arising from unmatched or invalid proxy NDCs during the CY 2006 upload process as well as the time-consuming and cumbersome nature of establishing and assigning proxy NDCs. CMS has developed the Formulary Reference NDC File in response to these issues. While this new process may require additional work in preparing for the initial CY 2007 HPMS formulary upload, it is designed to make the process more efficient and reduce the overall amount of effort needed to build and maintain formulary files moving forward.

Question 3

Q: Will the NDC still serve as a proxy code representing all strengths and formulations of a given drug or product?

A: No. For CY 2007, a unique proxy code will be assigned to each drug at the brand name, generic name, dosage form, and strength level. This will obviate the need for organizations to submit duplicate NDCs/codes due to tiering, prior authorization, step therapy, and/or quantity differences for the same drug. Formulary files should include the Formulary Reference NDC code for each unique drug (brand name, generic name, dosage form, strength) that will be included as a formulary drug.

Question 4

Q: Why are drugs excluded from Part D not included on the file?

A: Enhanced alternative plans that wish to offer Part D excluded drugs as part of a supplemental benefit will be provided specific instructions on how to submit these drugs to CMS in forthcoming guidance. Base formulary files will not contain excluded Part D drugs since, at the time of formulary review, organizations will not have cross-walked formularies to plan benefit packages.

Question 5

Q: Will Plans be able to submit alternative Reference NDCs for existing drugs on the Formulary Reference NDC File?

A: No. The new proxy code will represent the only NDC code that may be included on a formulary file for a given product at the brand name, generic name, dosage form, and strength level. Only those proxy NDC codes appearing on the Formulary Reference NDC File will validate upon HPMS formulary upload. This will streamline the formulary submission upload and validation process, as well as reduce the extent of formulary file modifications and subsequent reviews by CMS.

Question 6

Q: How will the Formulary Reference NDC File be updated?

A: As new drugs, dosage forms, or strengths become available, CMS will add them to the Formulary Reference NDC File with a unique proxy code. Likewise, drugs that become obsolete will be removed from the Formulary Reference NDC File. These additions and deletions will occur prior to each HPMS formulary upload cycle.

Question 7

Q: What if a drug cannot be found on the Formulary Reference NDC File?

A: In the event that a Part D covered drug does not appear on the Formulary Reference NDC File, an organization may request that the drug be considered for inclusion in the Formulary Reference NDC File. Organizations should submit an email to PartDformularies@cms.hhs.gov requesting that a particular drug (brand name, generic name, dosage form, strength) be included in the Formulary Reference NDC File. The subject line of the email should refer to the Formulary Reference NDC File. The Formulary Reference NDC file will be updated prior to each HPMS formulary upload.

Question 8

Q: Is the proxy NDC in the Formulary Reference NDC File required for adjudication at the pharmacy?

A: Plans are not obligated to use the proxy NDC in their adjudication process. As stated in question 1, the proxy NDC only serves as a unique identifier for a drug and is not intended to endorse or otherwise encourage the use of a particular manufacturer.

Question 9

Q: How were the proxy NDCs chosen for each unique drug in the Formulary Reference NDC File?

A: The proxy NDCs appearing in the Formulary Reference NDC File were assigned by using an NDC corresponding to a calculated median Average Wholesale Price (AWP) for each unique drug (brand name, generic name, dosage form, strength).

Question 10

Q: Are organizations required to submit the proxy NDC contained in the Formulary Reference NDC File to DestinationRx for use within the Medicare Prescription Drug Plan Finder?

A: Yes, organizations will be required to submit the proxy NDC contained in the Formulary Reference NDC File submitted to DestinationRx for the Medicare Prescription Drug Plan Finder. This will alleviate issues encountered during CY 2006 regarding how obsolete NDCs are handled on the website.