

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



**CENTER FOR DRUG AND HEALTH PLAN CHOICE**

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TO: All Part D Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: CMS/FDA CY 2010 Non-Matched NDC List

DATE: October 21, 2009

The Centers for Medicare & Medicaid Services (CMS) has posted the updated CY 2010 Non-matched NDC list with national drug codes (NDCs) provided by the Food and Drug Administration (FDA), on the CMS website at:

[www.cms.hhs.gov/PrescriptionDrugCovContra/03\\_RxContracting\\_FormularyGuidance.asp](http://www.cms.hhs.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp). CMS will use this updated list to establish new edits beginning on or around January 1, 2010 that will reject prescription drug event (PDE) submissions from Part D sponsors for NDCs identified on the list. The Non-matched NDC list was developed as part of an ongoing joint initiative between CMS and FDA to increase transparency and clarity with respect to the regulatory status of marketed prescription drug products. Please refer to the [2010 CMS Call Letter](#) for a more detailed discussion of the initiative.

CMS cannot emphasize enough that we expect Part D sponsors to do more than simply use the CY 2010 Non-matched NDC list to establish new point-of-sale edits and pharmacy messaging for January 1, 2010. Part D sponsors should evaluate the updated list with respect to their formularies and determine if it could negatively impact their enrollees. If Part D sponsors determine that the Non-matched list includes any NDCs for covered products on their formulary, we expect Part D sponsors to manage their supply chain and take steps to get such products listed on the FDA NDC Directory by reaching out to manufacturers, labelers, repackers, or distributors. Moreover, Part D sponsors should communicate with their pharmacies and PBMs so that the pharmacies and PBMs also can take steps to prepare for any changes, including working with suppliers to ensure unlisted products are not offered to Medicare beneficiaries.

In response to other questions and comments that we have received since the posting of the initial pilot Non-matched NDC list in May, we offer the following clarifications:

- This list cannot be used to determine a drug's status as approved or unapproved.
- This list may not identify all NDCs not properly registered and listed with the FDA.

- Not all NDCs on the Non-matched NDC list are otherwise Part D drugs (e.g. some NDCs are for excluded drugs) and, therefore, proper listing of such products with the FDA will not necessarily result in coverage under Part D.
- Edits will only apply to PDEs with dates of service on or after January 1, 2010.
- CMS plans to update the list at least twice during the 2010 plan year by deleting NDCs that have been registered and listed with the FDA since the fall 2009 posting of the list and removing associated PDE edits. Removal of edits will apply both retrospectively and prospectively for all dates of service.
- Additional NDCs will not be added to the CY 2010 Non-matched NDC list during the 2010 plan year.
- We expect Part D sponsors to rely on the FDA NDC Directory to determine when NDCs get listed and not wait for CMS to update the Non-matched NDC list. While this may result in a time lag between our edit updates and the FDA NDC Directory listings, which could require resubmission of previously rejected PDEs, Part D sponsors should NOT wait to remove associated point-of-sale edits once NDCs are listed with the FDA.
- At this time, CMS is not considering making any changes to the Formulary Reference File or accepting negative formulary change requests in relation to the Non-matched NDC list.
- For questions or concerns about FDA's NDC Directory, FDA's drug listing procedures, or possible inaccuracies in the Non-Matched NDC list, please contact FDA's Drug Registration and Listing Team at (301) 210-2897 or e-mail [nonlisted@fda.hhs.gov](mailto:nonlisted@fda.hhs.gov).
- For questions or concerns about PDE reject edits for NDCs listed on the Non-Matched NDC list, please e-mail [PartD\\_NDC@cms.hhs.gov](mailto:PartD_NDC@cms.hhs.gov).