

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



CENTER FOR MEDICARE

DATE: October 22, 2010

TO: All Part D Sponsors

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

SUBJECT: CMS/FDA CY 2011 Non-Matched NDC List

The Centers for Medicare & Medicaid Services (CMS) has posted the initial CY 2011 Non-matched NDC list with national drug codes (NDCs) provided by the Food and Drug Administration (FDA), on the CMS website at:

http://www.cms.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp#TopOfPage.

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. CMS expects to update the list one time in December 2010 with deletions for new listings on the FDA NDC Directory since October 2010. We will use the updated December list to establish new edits beginning on or around January 1, 2011 that will reject prescription drug event (PDE) submissions from Part D sponsors for NDCs identified on the list.

We remind Part D sponsors that:

- 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, 2011.
- Additional NDCs will not be added to the CY 2011 Non-matched NDC list during the 2011 plan year.
- CMS will update the list periodically during the 2011 plan year by deleting NDCs that have been registered and listed with the FDA since the December 2010 posting of the list and

remove associated PDE edits. Removal of edits will apply both retrospectively and prospectively for all dates of service.

- 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.
- Part D sponsors should do more than simply use the CY 2011 Non-matched NDC list to establish new point-of-sale edits and pharmacy messaging for January 1, 2011. They should evaluate the list with respect to their formularies and determine if it could negatively impact their enrollees. We expect Part D sponsors to manage their supply chain reach out to manufacturers, labelers, repackers, or distributors to get products listed on the FDA NDC Directory.
- 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.
- 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.
- 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.