DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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MEDICARE PLAN PAYMENT GROUP

DATE: September 12, 2011

TO: All Prescription Drug Plans

FROM: Cheri Rice /s/
Director

SUBJECT: **Update on Part D National Drug Code Edits**

The purpose of this memorandum is to update Part D sponsors on the Centers for Medicare & Medicaid Services' (CMS) approach to editing national drug codes (NDCs) submitted on prescription drug events (PDEs) under the Part D program. Specifically, this memo provides Part D sponsors with information on CMS' PDE editing logic used to identify applicable drugs covered by manufacturer discount agreements under the Coverage Gap Discount Program (Discount Program). Ultimately, PDE edits are not CMS coverage determinations and it remains the responsibility of Part D sponsors to make Part D drug determinations and applicable drug determinations. Nevertheless, with the recent changes to the Food and Drug Administration's (FDA) NDC Directory, we are providing this update to explain how CMS is using, and plans to use, publicly available FDA information (or lack of FDA information) when establishing PDE edits for Discount Program.

In June 2011, the FDA began posting the new FDA NDC Directory at http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm. The new Directory identifies only those NDCs that have been electronically listed with the FDA and includes additional data fields such as marketing category, marketing start date, and marketing end date. While the FDA will only update the new Directory, the FDA also posted a final old NDC Directory on June 1, 2011, that includes both electronically listed and paper listed NDCs. This old Directory will no longer be updated with NDC additions, deletions, or changes.

With the goal of transitioning to the new FDA NDC Directory as the sole official source of NDCs for drug products on the market that are required to be listed with the FDA, including the source for marketing category, marketing start date, and marketing end date, CMS will establish PDE edits for the Discount Program based upon the new FDA NDC Directory downloadable files using the following logic:

PDE edits for NDCs that have never been listed on the new or old FDA NDC Directory on or after January 1, 2011:

- CMS will not accept PDEs with coverage gap discounts for NDCs that have never been listed on the new FDA NDC Directory or old FDA NDC Directory with an NDA or BLA marketing category on or after January 1, 2011.[1]

- As of July 1, 2011, PDE edits for the coverage gap discounts are based upon the marketing category specified on the new FDA NDC Directory, not the FDA Orange Book, except that PDE edits for the coverage gap discounts are based upon the marketing category specified in the FDA Orange Book for NDCs listed ONLY on the old FDA NDC Directory.

PDE edits for NDCs that were listed on the new FDA NDC Directory as of June 1, 2011, and have since been removed:

- CMS will not accept PDEs with coverage gap discounts for dates of service after the marketing end date specified in the new FDA NDC Directory or for dates of service beginning on the 1st day of the month following the month the NDC was removed from the new FDA NDC Directory if no marketing end date is specified. CMS will implement this edit even though the NDC could still remain in the old FDA NDC Directory since it is no longer being updated.

PDE edits for NDCs that were listed on the old FDA NDC Directory as of January 1, 2011, and were removed prior to June 1, 2011 final posting and not listed on the new FDA NDC Directory:

- CMS will not accept PDEs with coverage gap discounts beginning the 1st of the month following the month the NDC was removed from the old FDA NDC Directory for dates of service on or after the 15th of the month that the NDC was removed. For any NDCs that were removed from the old FDA NDC Directory on the final June 1, 2011 posting, CMS will implement the PDE edit beginning on July 1, 2011 for dates of service on or after June 1, 2011.

PDE edits for NDCs with duplicate and conflicting entries:

- If an NDC is listed on both the new FDA NDC Directory and old FDA NDC Directory, CMS will rely on the marketing category specified in the new NDC Directory, not the FDA Orange Book, to establish the PDE edit.

- If an NDC is listed on the new FDA NDC Directory ONLY with duplicate entries having different marketing start dates:

[1] This applies to both inner-pack (inner-layer) and outer-pack NDCs.

--CMS will not edit on the start date if both marketing start dates are earlier than 1/1/2011.

--CMS will use the earliest marketing start date for PDE editing if an NDC has conflicting start dates on or after 01/01/2011.

- If an NDC is listed on the new NDC Directory ONLY with duplicate entries having different marketing end dates:

  -- CMS will use the latest marketing end date for PDE editing if an NDC has conflicting marketing end dates.

- If an NDC is listed on the new NDC Directory ONLY with duplicate entries having different marketing categories:

  --CMS will edit the NDC as an ANDA if the new FDA NDC Directory specifies ANDA as one of the marketing categories.

  --CMS will edit the NDC as NDA or BLA if the new FDA NDC Directory specifies NDA or BLA as one of the marketing categories and the other marketing category/categories is/are not specified as ANDA.

- If an NDC is listed on the old FDA NDC Directory ONLY with duplicate entries having different marketing categories, CMS will edit the NDC as an ANDA if FDA Orange Book specifies ANDA as one of the marketing categories.

- If an NDC is listed on the old FDA NDC Directory ONLY with duplicate entries having different marketing categories, CMS will edit the NDC as an NDA if FDA Orange Book specifies NDA or BLA if the old FDA NDC Directory specifies BLA and the other marketing category/categories is/are not specified as ANDA.

PDE edits for drug products that are listed on the new FDA NDC Directory and have marketing category changes (e.g. NDA to ANDA or ANDA to NDA).

- CMS will NOT accept PDEs with coverage gap discounts submitted on or after the 1st of the month following the month the NDC marketing category changed in the new FDA NDC Directory to a non-applicable drug (e.g. ANDA) for dates of service on or after the 15th of the month in which the change occurred.

- CMS will accept PDEs with coverage gap discounts beginning the 1st of the month following the month the NDC marketing category changed in the new FDA NDC Directory to an applicable drug covered by a Discount Program Agreement for dates of service on or after the 15th of the month in which the change occurred.

- CMS will NOT accept PDEs with or without coverage gap discounts beginning the 1st of the month following the month the NDC marketing category changed in the new FDA NDC Directory to an applicable drug that is NOT covered by a Discount Program Agreement for dates of service on or after the 15th of the month in which the change occurred.

Looking Ahead

CMS currently rejects PDEs with NDCs that are identified on the CMS non-matched list or PDEs with dates of service on or after 01/01/2008 with NDCs that have not been active in either First DataBank or MediSpan since 2008 (see March 28, 2011 HPMS memo) and are no longer present on First DataBank or MediSpan and are not listed on the old or new FDA NDC Directory. At this time, CMS will not be implementing new PDE reject edits for NDCs that are not listed (and are required to be listed) on the new FDA NDC Directory, but we will likely move in this direction in the near future. Until that time, we do not plan to update the CMS non-matched list for 2012 with new NDCs. Instead, we expect Part D sponsors to pay for NDCs that are not listed on the new FDA NDC Directory (and not already rejecting on PDEs as specified above) only if they have good reason to believe that such NDCs represent Part D drug products that are still marketed and likely will be electronically listed with the FDA (e.g. currently listed on the FDA Online Label Repository at http://labels.fda.gov with an NDA or BLA marketing category), or otherwise the FDA does not list on the new FDA NDC Directory, such as insulin syringes. We also expect Part D sponsors to continue to reach out to manufacturers that have not electronically listed their drug products and inform them of the need to do so in order to ensure continued eligibility for coverage under Part D. Finally, we remind Part D sponsors that we believe very few, if any, unapproved drug products satisfy the definition of a Part D drug and, therefore, caution Part D sponsors to make independent determinations of Part D drug status on all unapproved drug products including those products listed on the new FDA NDC Directory.

Please submit any question on this guidance to pdejan2011@cms.hhs.gov.