DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE
MEDICARE PLAN PAYMENT GROUP

DATE: May 14, 2012

TO: All Part D Plan Sponsors

FROM: Cheri Rice, Director
                    Medicare Plan Payment Group

**SUBJECT: Implementation starting September 1, 2012 of PDE Editing using the
                    FDA Online Label Repository**

Beginning September 1, 2012, CMS will use the FDA's Comprehensive NDC Structured
Product Labeling (SPL) Data Elements file (NSDE) to edit PDEs. Specifically, CMS will
reject prescription drug event (PDE) submissions with all of the following:

- Drug Coverage Status Code of 'C'
- Dates of service (DOS) on or after September 1, 2012
- National drug code (NDC) not listed on the NSDE file, or NDC listed on NSDE file
  with a Marketing End Date prior to DOS

CMS will not subject these submissions to further PDE processing unless the NDC
represents a covered Part D drug, such as medical supplies associated with the injection of
insulin, that generally are not listed on the FDA NDC Directory. PDEs rejected at this point
in the PDE editing process will either receive the edit "The NDC is not found on the NSDE"
or "The DOS is after the Marketing End Date on the NSDE." The NSDE file can be found at
http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm.

Currently, CMS uses First Databank and MediSpan to edit NDCs on PDEs before the PDE
continues through the PDE editing process. If the NDC is not found on First Databank and/or
MediSpan files, the PDE is rejected with edit 735 "The NDC Code does not match a valid
code on the NDC database." Starting on September 1, 2012, CMS will begin using the NSDE
file prior to First DataBank and MediSpan for the initial editing of NDCs on PDEs with dates
of service on or after September 1, 2012, and, reject any PDE submissions with NDCs not
found on the NSDE as described above.

In addition, beginning September 1, 2012, CMS will use the NSDE to make marketing category determinations for the Coverage Gap Discount Program (Discount Program). The marketing category determines if a Part D drug is an "applicable drug" under the Discount Program. CMS currently uses data from both the New FDA NDC Directory and the Old FDA NDC Directory to establish marketing category edits for Discount Program editing. Since we will only allow PDEs with NDCs that are listed on the NSDE (except as noted above), this change will ensure that marketing category edits are always consistent with the information on the latest upload of the NSDE and will streamline the process for establishing these edits.

PDE editing using the NSDE will become effective on September 1, 2012. Although the FDA will update the NSDE file daily, CMS will use the NSDE file posted on August 15, 2012, to initially update our editing files on September 1, 2012. Going forward, CMS will use the NSDE file posted on the 15th of each month to update our editing files on the 1st of each following month. If the 15th falls on a non-business day, CMS will use the NSDE file posted on the next business day. Discount Program editing for PDEs with dates of service prior to the September 2012 release date will still use both the New FDA NDC Directory and Old FDA NDC Directory for marketing category determinations. CMS will continue updating our Discount Program editing files used for editing PDEs with dates of service prior to the September 2012 release date with the New FDA NDC Directory through May 2013.

Coverage Gap Discount Program

CMS will begin by using the following data elements downloaded on August 15, 2012, from the NSDE file: 11-digit NDC, Marketing Category, Marketing Start Date, and Marketing End Date. After updating our editing files on the 1st of each month with these data elements, CMS will apply the following logic:

- CMS will edit at the 11-digit NDC level, including inner-layer and outer-pack 11-digit NDCs.
- CMS will reject PDEs with coverage gap discounts for NDCs without NDA or BLA marketing categories.
- CMS will edit PDEs with coverage gap discounts using the PDEs date of service and the NDCs Marketing Start and End Dates, if available.

CMS understands that sometimes conflicting information may occur on the NSDE file. Below is a chart that outlines how CMS will edit NDCs when NDCs are listed more than once with different information:

Discrepancy	NDC 1	NDC 2	Data Used for PDE Editing
*Marketing Category	*ANDA*	*NDA/BLA*	*ANDA*
Marketing Category	*ANDA*	*not NDA/BLA, e.g. Unapproved drug other*	*ANDA*
Marketing Category	*NDA/BLA*	*not ANDA, e.g. Unapproved drug other*	*NDA/BLA*
Start Date	*03/04/2012 (NDA)*	*07/29/2012 (NDA)*	*03/04/2012*
End Date	*09/30/2012*	*11/30/2012*	*09/30/2012*

*For example, if an NDC on the NSDE file has a marketing category of ANDA, and, the same NDC is listed again on the NSDE file with an NDA or BLA, CMS will use the ANDA Marketing Category for PDE editing.

Timing Issues

CMS also realizes that timing may be an issue between the dates of PDE submissions and updates to the NSDE file used for PDE editing. Below are scenarios to help clarify these types of circumstances:

- An NDC listed on the NSDE file as of the 15th of each month will be used for PDE editing starting the 1st of the following month.
    - o A new drug product (NDC) enters the market on August 19, 2012.
    - o The NDC first appears on the November 15, 2012, NSDE file.
    - o CMS editing file will implement the NDC on December 1, 2012.
    - o CMS will reject PDEs for this NDC up to December 1, 2012.
    - o PDEs for this NDC, regardless of date of service, should be resubmitted on or after December 1, 2012.

- The Marketing Category listed on the NSDE file as of the 15th of each month will be used for PDE editing starting the 1st of the following month.
    - o NDC is listed on the August 15, 2012, NSDE file with an ANDA.
    - o CMS editing file will implement an ANDA on September 1, 2012.
    - o NDC changes its Marketing Category to an NDA on the September 15, 2012, NSDE file.
    - o CMS editing file will implement an NDA on October 1, 2012.

- o CMS will reject PDEs for this NDC with coverage gap discounts submitted up to October 1, 2012.
- o PDEs that receive this rejection, regardless of date of service, should be resubmitted on or after October 1, 2012.

We would like to reiterate, as in past guidance, that 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. Therefore, we want to further emphasize that, if a sponsor believes that information on the NSDE file is incorrect, the sponsor must notify the FDA at spl@fda.hhs.gov and contact the manufacturer to update the NDC information provided on the NSDE file. Once the information is updated on the NSDE file and implemented on the CMS editing files, sponsors should resubmit rejected PDEs.

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