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MEDICARE PLAN PAYMENT GROUP

DATE: October 25, 2012

TO: All Part D Plan Sponsors

FROM: Cheri Rice, Director
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SUBJECT: Further Information Related to PDE editing using the NSDE

Since the implementation of PDE editing using the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE), CMS has received additional input and questions from both sponsors and manufacturers. This memo is intended to highlight some of those topics and provide some refresher information. Please continue to submit future questions/issues to CMS at PDEJan2011@cms.hhs.gov.

Part D covered drugs not present on the NSDE

The presence or absence of an NDC on the NSDE and the accuracy of the listing information is NOT a coverage determination. Part D sponsors are expected to do their due diligence in determining if a drug is a Part D covered drug and is currently marketed. CMS expects Part D sponsors to reach out to manufacturers regarding missing or inaccurate information on the NSDE.

Our August 2012 guidance was intended to make it clear that not all NDCs absent from the NSDE file should be treated the same but rather more work needs to be done by the Part D sponsor before implementing POS edits to ensure access to formulary drugs. For example:

- If a formulary drug is available from multiple labelers and some of the labelers do not have some or all of their NDCs listed on the NSDE, then it would be permissible to establish POS edits on just the NDC-11s that are not listed. This would not be a negative formulary change because the drug is still available under other NDC-11s that are listed on the NSDE. It is incumbent on the sponsor or its PBM to let their pharmacies know that these edits are NDC-11 specific (through POS messaging or otherwise) and do not mean that all NDCs for a specific formulary product are not covered (only the unlisted ones).

- If no NDC-11s are listed on the NSDE for a formulary drug, the sponsor needs to determine if the drug product still exists on the market—this requires outreach to the manufacturer. If no unexpired product for the NDC-11 is still on the market, POS edits

should be implemented and retrospective notice sent to the enrollee that the product is no longer on the market. If the product is still on the market with unlisted NDCs only, the plan should continue to cover and continue to reach out to the manufacturer to get the NDCs listed.

CMS expects Part D sponsors to update their POS edits based upon the NSDE file more frequently than CMS' monthly update for PDE editing purposes. The NSDE file is updated daily by the FDA and while a monthly lag is manageable for updating PDE edits by CMS, we do not believe such a lag is appropriate for POS edits that potentially affect beneficiary access to new drugs and prevent claims for expired NDCs.

In addition, drug manufacturers with questions regarding missing or inaccurate information on the NSDE should contact the FDA to add or update the listing information. CMS does not maintain the data in the file and cannot coordinate any changes. You can locate contact information for the FDA's Drug Registration and Listing at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm254946.htm.

Trends in the content of the NSDE

CMS has been monitoring the content of the NSDE since the May 14, 2012 memo announcing the September 1, 2012 implementation date. This included a comparison of NDCs submitted in 2012 for accepted PDES with DOS in 2011 and 2012 versus NDCs present on the NSDE. At the time of implementation on September 1, 2012, only 0.55% of accepted PDEs submitted since January 1, 2012 for DOS in 2011 and 2012 contain NDCs not listed on the NSDE. Currently, only 0.16% of accepted PDEs submitted since January 1, 2012 for DOS in 2011 and 2012 contain NDCs not listed on the NSDE.

CMS also conducted outreach to manufacturers concerning NDCs not present on the NSDE, especially those with a historically higher volume of accepted PDEs. In the months preceding implementation, we saw a drastic decrease in the number of NDCs that were not present on the NSDE, and continue to see decreases even after the September 1, 2012 implementation date.

CMS will continue to monitor the content of the NSDE and hope to continue to see this trend as manufacturers continue to electronically list their drug products.

Coding Error

As stated in the September 10, 2012 HPMS memo, there was a PDE processing error related to the NSDE impacting Part D Sponsors in the beginning of September. The coding error was causing PDEs containing an NDC with a non-NDA/BLA Marketing Category to be rejected by CMS with Edit 747 which states "The NDC was found on the current FDA NDC SPL Data Element file, but is not effective for the given DOS." The rejection only occurred for PDEs with DOS on or after September 1, 2012, as only these PDEs are edited against the NSDE.

The issue was corrected and sponsors should resubmit any PDEs that were affected if they have not done so already.

PDE Editing and New Edits Related to the NSDE (746 & 747)

Two new edits have been created pertaining to PDE editing using the NSDE – Edit 746 and 747. The following describes when these new edits will be issued:

- PDEs with DOS on or after September 1, 2012 for drugs with a coverage status code of 'C' that do not have an NDC on the NSDE will be rejected and receive Edit 746 which states "This NDC is not found on the current FDA NDC SPL Data Element file".

- PDES with DOS on or after September 1, 2012 for drugs with a coverage status code of 'C' that do have an NDC on the NSDE but DOS is after the Marketing End Date will be rejected and receive Edit 747 which states "This NDC is found on the current FDA NDC SPL Data Element file, but is not effective for the given Date of Service".

- PDES with DOS on or after September 1, 2012 for drugs with a coverage status code of 'C' that do have an NDC on the NSDE but the DOS is before the Marketing Start Date will be rejected and receive Edit 747 which states "This NDC is found on the current FDA NDC SPL Data Element file, but is not effective for the given Date of Service".

Please note that implementation of PDE editing using the NSDE is a new initial editing step to the previous PDE editing process. Any editing that was completed prior to September 1, 2012 is still completed on all PDEs. For covered drugs with a DOS on or after September 1, 2012, the only changes are: 1) the NDC must be listed on the FDA's NSDE file and fall within the current marketing dates to continue through CMS' PDE editing process; and 2) the NSDE will now be used to determine marketing categories.

The following explains the initial editing steps of a PDE in relation to the NSDE depending on the DOS of the PDE:

- **DOS prior to 9/1/2012**: CMS will continue to use First Databank (FDB) and Medi-Span (MDDB) to edit NDCs before the PDE continues through the PDE editing process. If the NDC is not found on FDB and/or MDDB files, the PDE is rejected with edit 735 which states "The NDC Code does not match a valid code on the NDC database."

- **DOS on or after 9/1/2012:** CMS will use the NSDE file prior to FDB and MDDB for the initial editing and reject any PDE submissions with NDCs not found on the NSDE. If the NDC is not listed on the NSDE or does not fall within the current marketing dates, it will receive edit 746 or 747, respectively. If the NDC is listed on the NSDE file, the PDE will proceed through processing to determine if the NDC is found on FDB and/or MDDP. If not, the PDE will receive edit 735.

Q&A

Below are examples of questions CMS has received regarding implementation of the PDE editing using the NSDE. We feel these may be helpful to all sponsors.

Q1: When will a newly listed or updated NDC on the FDA's NSDE file be implemented by CMS in the PDE editing process?

A: CMS obtains the NSDE file from the FDA site on the 15th of each month for implementation on the 1st of the following month. If the 15th falls on a non-business day, CMS will use the NSDE file posted on the next business day. For example, the information on the NSDE file obtained by CMS on October 15th is implemented in the DDPS PDE editing files on November 1st for PDE editing from November 1st through November 30th. On December 1st, the DDPS PDE editing files will use the NSDE file obtained on November 15th for PDE editing from December 1st through December 31st. The FDA updates the NSDE file daily. Any updates made to the NSDE on the FDA site will be implemented in the next CMS download cycle.

Example 1: An NDC is added to the NSDE on October 16th. CMS will obtain an updated NSDE from the FDA site on November 15th and any changes will be implemented in the DDPS system for PDE editing on December 1st.

Example 2: An NDC is added to the NSDE on November 4th. CMS will obtain an updated NSDE from the FDA site on November 15th and any changes will be implemented in the DDPS system for PDE editing on December 1st.

Q2: How can a sponsor identify what data CMS is using in their current editing files for PDEs edited with the NSDE file? What steps can a sponsor take to evaluate the receipt of Edit 746 and 747?

A: As detailed in Q1 above and the May 14, 2012 HPMS memo, CMS has stated the methodology that will be used to determine the date upon which a monthly NSDE file will be obtained from the FDA site and implemented into the DDPS editing files. The NSDE is a publicly available file. Any interested party, by downloading the NSDE file on the same day as CMS, would be able to reference that file to evaluate any NSDE-related PDE edit errors for the following full month. This is not required by sponsors but is a helpful suggestion.

The FDA updates the NSDE file on their site daily. If a sponsor verifies the information for an NDC is accurate on the FDA site, it is possible to verify if the NDC information will be updated in the next month's DDPS editing file if the mid-month NSDE file was obtained by the sponsor from the FDA.

Example: A PDE is rejected with Edit 746 (NDC not listed on NSDE) on November 10th. The sponsor verifies that the NDC is listed currently on the FDA site in the NSDE file. However, the sponsor is not aware that the manufacturer only recently listed the NDC on November 5 and,

therefore, is not present in the current DDPS PDE editing files which uses the October 15th NSDE file. If the sponsor was regularly obtaining the mid-month file, they would be able to verify that the NDC was not on the CMS mid-month file obtained on October 15th for PDE editing November 1-30, but will be on the CMS mid-month file to be obtained on November 15th for PDE editing December 1-31. The sponsor will be able to resubmit the rejected PDE on or after December 1.

Q3: There are 2 files on the FDA SPL Downloadable Data page – a .csv file and a .txt file. Which file is CMS obtaining?

A: CMS is obtaining the .csv file available on the FDA site for implementation into the DDPS PDE editing files. The .txt file only contains information on actively marketed NDCs. As PDEs can be submitted up to 37 months after the end of the contract year, it is important to maintain information on all NDCs and not just currently marketed NDCs.

Q4: What does the marketing end date represent?

A: As stated on the FDA website, the marketing category end date is the expiration date of the last lot distributed. Products that are actively being marketed will not have a marketing end date. Products that are no longer manufactured may have a future end marketing date for the expiration of the last lot distributed.