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December 21, 2007

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development - C
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Ms. Harkless,

This letter accompanies Medco's comments on the draft 2009 Plan Benefit Package (PBP) and Formulary Submission package. The enclosed comments reflect concerns and questions that our plan had upon initial review of this draft documentation.

If you have any questions regarding these concerns, please contact Laura Carr, Compliance Senior Manager directly at 704/919-1609 or laura_carr@medco.com.

Regards,

Laura Carr

Laura Carr
Senior Compliance Manager
Medco Health Solutions, Inc.

Encl.

Medco's comments to the draft 2009 Plan Benefit Package (PBP) and Formulary Submission package

Section Requirement	Medco Question/Issue
Home Infusion Drug File	Could CMS please clarify the frequency of this file submission, would plans have to submit this file on a monthly basis or only when changes are made to the file? Is the submission of this file the same as other formulary files, or is a different process required? Is there a rationale for having this as a separate file from the formulary flat file, the additional file requirement is more burdensome to plans?
OTC Drug File	Could CMS please clarify the frequency of this file submission, would plans have to submit this file on a monthly basis or only when changes are made to the file? What NDCs should plans utilize to identify that a drug is covered by the plan? In previous submissions plan utilized CMS proxy NDCs, with the proposed 2009 submission process there will not be proxy NDCs for these drugs. Medco would like to clarify with CMS if a plan utilizes First Data Bank to obtain NDCs and not Medispan, will the plan receive rejections for NDCs that do not exist in the Medispan system?
Excluded Drugs File	Could CMS please clarify the frequency of this file submission, would plans have to submit this file on a monthly basis or only when changes are made to the file? What NDCs should plans utilize to identify that a drug is covered by the plan? In previous submissions plan utilized CMS proxy NDCs, with the proposed 2009 submission process there will not be proxy NDCs for these drugs. Medco would like to clarify with CMS if a plan utilizes First Data Bank to obtain NDCs and not Medispan, will the plan receive rejections for NDCs that do not exist in the Medispan system? The proposed system stipulates that a tier has to be indicated for the Excluded Drug File. However, most plans are set up where there is no specific tier for these drugs; there is generally a non-d copay that a plan has members pay for these drugs. This non part d copay isn't set to a particular tier 1,2,3 etc. Are plan sponsors required to indicate a non-d tier on the PBP submission process?

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December 17, 2007

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

To Bonnie L. Harkless:

MedImpact has reviewed the draft of the 2009 Plan Benefit Package (PBP) and Formulary Submission guidance distributed on 10/26/07. MedImpact is a Pharmacy Benefits Management company that currently manages 31 formularies for 27 health plans nationally. MedImpact respectfully submits the following comments, suggestions and questions on the specifications for the items listed below.

1. Appendix C - CY 2009 Excluded Drugs Record Layout 10092007.doc states:

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NDC	CHAR Always Required	11	11-Digit National Drug Code	00000333800

Appendix C - CY 2009 Over the Counter Record Layout 10092007.doc states:

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
NDC	CHAR Always Required	11	11-Digit National Drug Code	00000333800

The new files for excluded drugs and OTCs suggest use of a NDC versus a proxy NDC. Would you please confirm the following?

Question 1: Will CMS provide a reference proxy NDC list for excluded and OTC drugs?

Question 2: If no, does CMS expect all detailed NDCs to be included in these files, or a plan-defined "reference" NDC for these files?

Question 3: How will CMS treat any changes to these files? Will CMS perform a similar validation and comparison of these files, including reviewing for negative changes, as is currently done with the main formulary ASCII files?

Comment: In the past, CMS has experienced significant challenges deciphering inherent NDC level changes that are inevitable when using either detailed or plan-defined reference NDCs. NDC numbers can become obsolete and fall off of the file as well as drug names and strength formatting can change.

MedImpact strongly suggests that CMS either provide and use proxy NDCs, or refrain from implementing comparison reviews if plans are required to self-define NDCs. Significant programming hours will be involved to implement either solution; therefore, MedImpact is seeking clarification on this issue as soon as possible to allow for successful operational implementation for the supplemental 2009 formulary files.

2. Appendix C - CY2009 Formulary File Record Layout 100920007.doc states:

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Quantity_Limit_YN	CHAR Always Required	1	Does the drug have a quantity limit restriction?	1 = Yes 0 = No

Comment: In past years, CMS has required plans to qualify certain quantity limits as limited to new starts only. If CMS intends to continue reporting of this qualifier, MI recommends revision of this section title to Quantity_Limit_Type, and inclusion of a QL for new starts only choice to the available options. This change would bring greater consistency to the process and avoid extraneous and difficult to manage manual changes in associated word documents.

3. Appendix C - CY2009 Formulary File Record Layout 100920007.doc states:

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Step_Therapy_Type	CHAR Always Required	1	Does step therapy apply to this drug? Note: Prerequisite (Step 1) drugs should also have a value of 1 in this field.	0 = Not Part of a Step Therapy Program 1 = Step Therapy Applies 2 = Step Therapy Applies to New Starts Only

Comment: The Step_Therapy_Type field is part of the non-repeatable Step Therapy fields and thus applies to the proxy only. However, a proxy NDC may be involved in multiple step groups, indicated by multiple sets of repeating Step Therapy fields. To allow application of New Starts Only on a per Step Therapy basis the Step_Therapy_Type field should repeat for each step group. Alternately, if one field is to be used, guidelines must be very specific regarding field population especially in instances where a proxy is involved in multiple steps and multiple step values.

Question: Does the New Start Only choice apply to the step description overall or does the specificity filter down to the proxy NDCs within the step group? If the latter, must the first line agents within the step group carry a one or a two flag? This is somewhat unclear in the current draft's description.

4. Appendix C - CY 2009 Excluded Drugs Record Layout 10092007.doc states:

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Drug_Name	CHAR Always Required	200	Enter the name of the drug.	Diazepam

Appendix C - CY 2009 Over the Counter Record Layout 10092007.doc states:

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Drug_Name	CHAR Always Required	200	Enter the name of the drug.	Claritan

Question: Does CMS require the Brand Name or Generic Name to be reported on the excluded drugs and over the counter drugs files?

5. Appendix C - CY 2009 Home Infusion File Record Layout 10092007.doc states:

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
Proxy_NDC	CHAR Always Required	11	11-Digit National Drug Code Note: The NDCs included in this file must be a subset of the NDCs submitted in the Formulary file.	00000333800

Question: Will CMS allow plans to add and remove drugs from HI drugs list after the initial submittal?

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Question: If so, then if an existing CMS proxy is added to a plan's HI list will that proxy continue to be reported on subsequent ASCIIs? If not, then how will plans document the negative change that will appear to have taken place in their formulary ASCII file?

Due to the urgency for answers to these questions, especially surrounding treatment of NDC submissions in Excluded and OTC files, MedImpact will also be sending these questions to our CMS formulary contacts directly.

Thank you for the opportunity to comment.

Regards,
Kim Lowry

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