Zynchros™

From P & T To The Point-of-Care™

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

David Smith
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December 18, 2007

Re: Zynchros response to the proposed CMS 2009 formulary flat file changes

Preamble

Zynchros provides the Zynchros.com service to approximately 30 plan sponsors and PBMs acting on behalf of plan sponsors. For the 2008 plan year, a significant number of Part D formulary flat files were generated by the Zynchros.com system prior to being uploaded to HPMS.

As a result, Zynchros takes great interest in any changes to the formulary flat file record layout, since our system must be updated not only to reflect any changes in the file format itself, but also to update the user interface to collect the data provided in the file, and to validate the content and consistency of those data to reduce the chance of a failed submission or clinical review for our users.

After reviewing the proposed changes published under CMS-R-262 at:
www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/list.asp?listpage=1
Zynchros makes the following comments.

Formulary Flat File Changes

Change 1: Changes to Field Names

Zynchros has no issue with these changes. Since the field name labels are not used in the Formulary Flat File, this change has no impact on the Zynchros.com system or its users.

Change 2: Prior_Authorization_YN field

Zynchros.com will be required to update the formulary data collection interface to accommodate the changes to this field. For HPMS 2008, a single checkbox was used to indicate the yes/no status of the PA field. For 2009, we will need to allow the user to select one of the options:

- No Prior Authorization
- Prior Authorization Applies
- Prior Authorization Applies to New Starts Only
- Part D vs Part B Prior Authorization Only

For formulary validation, we seek additional information about how CMS will use this field, in particular:

- How should this field be validated in relation to the Prior_Authorization_Group_Desc field? In particular, does CMS expect that the value for the Prior_Authorization_Type field be consistent amongst all reference NDCs which have the same value for the Prior_Authorization_Group field?
- What changes to this field will constitute a negative change? Clearly, a change of 0 (No Prior Authorization) to any other value would be construed as a negative change, but for example will a change from 1 (Prior Authorization Applies) to 2 (Prior Authorization Applies to New Starts Only) be allowed?

We would anticipate the burden on the user to provide this additional data to be manageable.

Change 3: Step_Therapy_YN field

Zynchros.com will be required to update the formulary data collection interface to accommodate the changes to this field. For HPMS 2008, a single checkbox was used to indicate the yes/no status of the Step Therapy field. For 2009, we will need to allow the user to select one of the options:

- Not part of a step therapy program
- Step therapy applies
- Step therapy applies to new starts only

Unlike with Prior Authorization where each proxy NDC may be part of at most one named Prior Authorization Group, the formulary file format allows for a single NDC to be part of one *or more* named Step Therapy Groups.

We see the potential for confusion on the part of our health plan formulary managers on how to maintain consistency for the Step_Therapy_Type field for each NDC within each of the named Step Therapy Groups.

Should this change be enacted, we would seek the following clarifications from CMS on the use of this field:

- The record layout states that "Prerequisite (Step 1) drugs should also have a value of 1 in this field." However, the format allows for an NDC to be at Step 1 in one Step Therapy Group but at Step 2 of a second Step Therapy Group. How should plans set the value of this field in this situation?
- Does CMS expect consistency for this field amongst NDCs belonging to each Step Therapy Group? If so, we note that this implies that when a single NDC belongs to two Step Therapy Groups, then both groups must set all member NDCs on the formulary to either "Step therapy applies" *or* "Step therapy applies to new starts only".
- What is CMS's expectation regarding the use of this field after January 1 2009? Will the value "2 = Step Therapy Applies to New Starts Only" remain a valid value for NDCs added to the Formulary Reference File after submissions have been accepted?
- How will CMS handle changes in this field in subsequent formulary submissions? Logically, changing 1 → 0, 2 → 0, and 1 → 2 would constitute positive changes, and all others negative changes. We would recommend changing the numeric codes so that a decrease always represents a positive change to avoid confusion.

Plan-Specific Data Files

Free First Fill file

No issues.

Gap Coverage File

No issues.

Home Infusion Drug File

No issues.

OTC Drug File

We anticipate that there will be a significant burden on plans to collect and provide this information, especially since for the first time this requires plans to derive product information from a data source outside of the CMS Formulary Reference File. The fact that plans will draw this data from many sources (including e.g. Medi-Span, FDB) makes it likely to lead to inconsistencies. We would seek guidance from CMS on the following issues:

- What coding schemes will be considered valid for the Dosage_Form and Route_Of_Administration fields? The example gives codes familiar from the Medi-Span database rather than descriptions.
- Is a single representative NDC expected for each product / strength / dosage form / route covered, or are ALL potentially covered NDCs expected to be listed, including repackager NDCs?

Excluded Drugs File

Based on the limited information provided, we fear that this will pose an extremely significant burden on plans to provide this information. The following questions immediately arise:

- Are **all** products on the market excluded by the plan expected to be listed here, or just specific formulations related to proxy NDCs listed on the formulary flat file?
- NDC field: Is a single representative NDC expected for each product / strength / dosage form / route excluded, or are **ALL** potentially excluded NDCs expected to be listed, including repackager NDCs?
- For the "Tier" field, we assume this is intended to be the tier assigned the specific related proxy NDC on the formulary flat file. However, since this file is to be submitted at the plan level, what value should be provided when that product is listed at a different tier in different plan formularies?
- Will plans be required to update this file as products are added to / deleted from the Formulary Reference File during the plan year?

Conclusion

Zynchros welcomes the opportunity to comment at this early stage on the proposed changes to the formulary flat file layout and plan-specific flat files for the 2009 plan year. Advance notice allows us to plan our development schedule to ensure a minimum of disruption to our users preparing HPMS submissions with Zynchros.com and greatly reduces the risk of rejected submissions for our plan users. We look forward to confirmation of the planned changes at the earliest possible time so that our implementation schedules are confirmed and our users may plan their formulary preparation and submission schedules accordingly.

Sincerely,

David M Smith
VP, Product Management

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December 20, 2007

CMS, Office of Strategic Operations and Regulatory Affairs Division of Regulations Development – C
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Attn: Bonnie L. Harkless

Re: CY 2009 PBP and Formulary Files

Dear Ms. Harkless;

In response to CMS' proposed changes from the CY 2008 to CY 2009 PBP and Formulary Files I am submitting the below comments on behalf of Health Net, Inc.

1. On the addition of Home Infusion Drug File, OTC Drug File, & Excluded Drugs File.
   - Will CMS be providing clear direction on what/when we need to create these files?
     For example, the Excluded Drugs file - is that only for non-EGWP enhanced alternative plans?

2. For the Specialty Pharmacy YN field.
   - Will CMS be providing more clarification on how this field will be used? It is our understanding that this would be the Limited Distribution drugs. If CMS already knows what drugs are Limited Distribution why do we need to flag them in the file?

If you have any questions on our comments, please do not hesitate to call me directly at 1-916-463-9608 or email me at Alejandra.Clyde@healthnet.com.

Sincerely,

Alejandra Q. Clyde
Manager, Compliance & Reporting
Health Net, Inc.