DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
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PLAN OVERSIGHT AND ACCOUNTABILITY GROUP

TO: OMB

FROM: Lori Robinson, Director
Division of Plan Data

DATE: February 19, 2008

SUBJECT: Response to CMS-R-262 Comments

Thank you to everyone who provided comments on the Paperwork Reduction Act (PRA) package CMS-R-262. Please see below responses to your comments. Please note that comments submitted that are outside of the scope of this PRA package (i.e., such as those related to Summary of Benefits (SB) sentences or HPMS functionality) will not be addressed below.

1.) Section B – B-1 Screen
If possible, please separate outpatient hospital services and outpatient surgeries in the PBP.

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software.

2.) Section B
Incorporate an option to select standard FFS cost sharing for the Pan C similar to Selecting the defined standard benefit for Part D

CMS RESPONSE: CMS currently has given organizations the ability to select Medicare-defined cost sharing for Section B-1a (Inpatient Hospital – Acute), Section B-1b (Inpatient Psychiatric Hospital), Section B-2 (Skilled Nursing Facility), and Section D (Part B Deductible). CMS has determined that additional FFS questions in the PBP cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software.

3.) Section B – B -10b Screen
PBP Section B-1 Ob (transportation benefit): Please add Non-emergency Air Ambulance Service" as an additional choice to the following: Select Mode of Transportation far Plan approved location: Taxi, Bus/Subway, Van, and Other, describe when "Other, describe is chosen, the details that are in the "Notes" section do not print out on any reports except the Data Entry System Report, Non-emergency Air Ambulance Service should be

displayed on the Summary of Benefits Report that is generated in the PBP. The only way to do this is to make it one of the choices.

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software.

4.) Section B – B-4b Screen
Mandatory or Optional Supplemental Benefits for Worldwide coverage is no longer an option in the PBP.

CMS RESPONSE: The Worldwide coverage benefit is contained in Section B – 4a (Emergency Care) of the PBP.

5.) Section B – B-7A Screen

Having the in-network, urgently needed care added to this section confuses the benefit of "primary care" because in order to keep costs down and patient care quality high, members are encouraged to see their primary care provider for most of their care. Having the added differential for urgently needed care at a walk-in clinic that prints out on the summary of benefits as a minimum/maximum copayment for visits to for primary care makes the services appear to be just as expensive as specialist care. This is a necessary benefit to define, however I believe its placement is incorrect and should be in Section 7G – Other Health Care professionals.

CMS RESPONSE: CMS selected this location of the PBP for the new "In-network, urgently needed care" question so organizations would realize they could insert different cost-shares for the primary care physician (PCP) and the in-network, urgently needed care benefit. For CY2008, CMS required that these-cost shares be combined. Organizations may differ the minimum/maximum cost-sharing between the PCP and the in-network, urgently needed care benefit so that it is more advantageous for beneficiaries to go to the PCP.

6.) Section B – B-15 Screen
Maximum enrollee out of pocket costs periodicity is based on time. There is an "other option, but may not be clear on Summary of Benefits.

CMS RESPONSE: CMS has determined that additional types of periodicity selection in the PBP cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software.

7.) Section B – B-15C Screen
The Minimum/Maximum fields for copayment and coinsurance need to be moved on the page. Move the Maximum copayment field up to be in line with this question "Is there a copayment" and move the maximum coinsurance down to be in line with "Is there a coinsurance."

CMS RESPONSE: CMS has determined that it will keep the current screen format for the questions. Please note, only the questions that are enabled to the end user will be available, which will help minimize any data entry confusion.

8.) Section D – Optional Supplemental Screens
Optional Supplemental benefits are designated and defined in both Section B and Section D with no difference in questions, which is duplicate data entry.

CMS RESPONSE: CMS has determined certain benefits that may differ in Section B and in the Optional Supplemental benefit both require detailed data entry. The data entry screens are the same, but the cost sharing and benefits may differ. If the benefits offered in the Optional Supplemental Section mirror the data entry in Section B, PBP users have the ability to copy data from Section B into the Optional Supplemental data entry screens.

9.) Formulary - Prior Authorization File
Some Prior Authorization guidelines are very complex with multiple indications, with completely different criteria for each diagnosis. In the current record layout, plans are forced to enter different criteria for various indications in a single row. We recommend that CMS provide multiple rows per Prior Authorization Group.

CMS RESPONSE: The file format is row specific. Additional rows within a group description would cause a disconnect in the file. CMS will provide clarification in format that could accommodate request in current format.

10.). **Formulary – OTC Drug File**
What coding schemes will be considers valid for the Dosage_Form and Route_of_Administration fields?

CMS RESPONSE: Guidance is forthcoming in the CY 2009 HPMS Formulary Submission and Reports User Manual.

11.) Formulary – OTC Drug File
Is a single representative NCD expected for each product/strength/dosage form covered, or are ALL potentially covered NCDS expected to be listed?

CMS RESPONSE: Guidance is forthcoming in the CY 2009 HPMS Formulary Submission and Reports User Manual.

12.) Formulary – Excluded Drug File
Are all products on the market not covered by the plan expected to be listed here, or just specific formulations related to proxy NDCs on the formulary flat file?

CMS RESPONSE: Guidance is forthcoming in the CY 2009 HPMS Formulary Submission and Reports User Manual- For clarification of excluded drug categories, please refer to the Prescription Drug Benefit Manual, Chapter 6 Section 20.1. The excluded drug file should only contain drugs that fall into one of the listed categories. A couple of examples of the excluded drug categories are benzodiazepines and barbiturates.

13.) Formulary – Excluded Drug File
Is a single representative NCD expected for each product/strength/dosage form covered, or are ALL potentially covered NCDS expected to be listed?

CMS RESPONSE: Guidance is forthcoming in the CY 2009 HPMS Formulary Submission and Reports User Manual.

14.) Formulary – Excluded Drug File
For the "tier" field, we assume this is intended to be the tier assigned the specific 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?

CMS RESPONSE: Guidance is forthcoming in the CY 2009 HPMS Formulary Submission and Reports User Manual.

15.) Formulary – Excluded Drug File – Formulary Reference File
Will plans be required to update the formulary reference file as products are added/deleted from the Formulary Reference File during the plan year?

CMS RESPONSE: Guidance is forthcoming in the CY 2009 HPMS Formulary Submission and Reports User Manual. Please note that excluded drug NDC's are not on the Formulary Reference File.

16.) Formulary – Flat File Changes – Prior Authorization Field
How should this field be validated in relation to the Prior_Authorization_Group_Desc Field? Does CMS expect the value to be consistent against all reference NDCs?

CMS RESPONSE: CMS will clarify this relationship in the CY 2009 HPMS Formulary Submission and Reports User Manual.

17.) Formulary – Flat File Changes – Prior Authorization Field
What changes to this prior authorization field will constitute a negative change?

CMS RESPONSE: CMS will clarify this relationship in the CY 2009 HPMS Formulary Submission and Reports User Manual.

18.) Formulary – Flat File Changes – Step Therapy Field
The record layout states that Prerequisite (Step 1) drugs should also have a value of t in this field. However, the format allows for an NDC to be a Step 1 in one and a Step Therapy Group as a Step 2 in a second Step Therapy Group. How should plans set the values in these instances?

CMS RESPONSE: CMS will clarify this relationship in the CY 2009 HPMS Formulary Submission and Reports User Manual.

19.) Formulary – Flat File Changes – Step Therapy Field
What is CMS' expectation regarding consistency for this Step Therapy field amongst NDCs belonging to each Step Therapy Group?

CMS RESPONSE: CMS will clarify this relationship in the CY 2009 HPMS Formulary Submission and Reports User Manual.

20.) Formulary – Flat File Changes – Step Therapy Field
What is CMS' expectation regarding the use of the value "2 = Step Therapy Applies to New Starts Only" after January 1, 2009?

CMS RESPONSE: CMS will clarify these values in the CY 2009 HPMS Formulary Submission and Reports User Manual.

21.) Formulary – Flat File Changes – Step Therapy Field
How will CMS handle changes in this file for subsequent formulary submissions? Logically, there are few changes that would constitute positive changes.

CMS RESPONSE: CMS will clarify this in the CY 2009 HPMS Formulary Submission and Reports User Manual.

22.) Formulary – PA File Record Layout
How does the Part D Sponsor use this layout for a drug that has more than one indication?

CMS RESPONSE: CMS will clarify the format in the CY 2009 HPMS Formulary Submission and Reports User Manual.

22.) Formulary – PA File Record Layout
Does the maximum field length include spaces? The current length of 200 characters is not long enough.

CMS RESPONSE: CMS will provide new field lengths in the CY 2009 HPMS Formulary Submission and Reports User Manual.

22.) Formulary – PA File Record Layout
We see no field for references or Stand Care guidelines to be cited. Do we need to include references?

CMS RESPONSE: CMS will clarify this in the CY 2009 HPMS Formulary Submission and Reports User Manual.

If you have any questions regarding our responses, please contact Sara Walters at Sara.Walters@cms.hhs.gov or 410-786-3330. Thank you.