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MEDICARE DRUG BENEFIT AND C & D DATA GROUP

TO: OMB

FROM: Lori Robinson, Director
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DATE: December 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 A - A-1 Screen
Box titled "Is this a network plan?" How does the 'partial' option apply in 2010? It was our understanding that the MIPPA PFFS partial network requirements was not to take effect until 2011.

CMS RESPONSE: You are correct that the PFFS network requirements per MIPPA are not effective until 2011. However, organizations were allowed to begin offering partial network plans beginning in CY 2009.

2. Section A – A-1 Screen
Box titled "Do you cover Hospice Care?" Is this for the consultation only? Also, this may be clearer if placed in Section B (i.e. in the same relative area as the other benefits as it works in with the EOC)?

CMS Response: This question is only asked of B-only plan types and is not applicable to A/B health plans or stand alone prescription drug plans. CMS may consider in the future moving this question to Section B in the PBP.

3. Section A – A-3 Screen
Why are there so may telephone numbers? And why are most "optional"? What exactly is trying to be accomplished here?

CMS RESPONSE: The telephone numbers are entered in HPMS and downloaded with the PBP installation. Many of the phone numbers are indicated as optional because organizations have the option of including local phone numbers, but it is not a

requirement. These phone numbers are populated in the Summary of Benefit (SB) introduction, which provides beneficiaries with the appropriate phone numbers to call if they have questions about the plan.

4. Section B – 1A, 1B, and 2 (B Only Screens)
Why is there a separate set of Base screens for "B Only"? In what situation would Part B apply to Inpatient Hospital, Inpatient Psych, and SNF (this should only apply to Part A)?

CMS RESPONSE: Part B only plans have separate data entry screens for inpatient hospital, inpatient psych, and SNF because Part B plans may want to offer these traditional Part A services as a benefit under their plan, whereas Part A/B plans MUST offer at least the Medicare Part A benefits under their plan.

5.) Section B – Coinsurance Question
Boxes titled "Select the Coinsurance Coverage Basis for Medicare Covered Benefits:" Why does the list range from 4 to 6 various options; shouldn't these be consistent throughout?

CMS RESPONSE: The coinsurance coverage basis differed for different benefit categories because CMS deemed there were certain options that were not applicable to certain benefits. For CY 2010, the coinsurance coverage basis questions will be removed entirely from the PBP.

6. Section B – Service Categories 7B (Chiropractic Services), 7D (Physician Specialist), and 7 F (Podiatry Services)
Box should read: "Indicate Minimum Copayment **per visit** for Medicare Covered Benefits" "Indicate Maximum Copayment **per visit** for Medicare Covered Benefits"

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

7. Section B – 7E (Mental Health Services) and 7H (Psychiatric Services)
The "End Session Interval" boxes are out-of-line from the "Copayment" & "Begin Session" boxes. (For both Individual & Group)

CMS RESPONSE: In the production release of the software, we will make sure the data entry is lined up consistently throughout the software. Please note these are simply data entry mock-ups, not the final software product.

8. Section B – 7G (Other Health Professionals)
Please provide more explanation as to what professionals would fall here, including examples. Would such as convenient care centers, e-medicine or allergy injections fall in this category? Also, like CORF above, this does not fall out on the SB (or the EOC), so how would anyone know there was a benefit?

CMS RESPONSE: Please refer to the "category description" section of the PBP, which indicates:

#7g Other Health Care Professional Services

Includes professionals engaged in the delivery of health care who are licensed, practice under an institutional license, are supervised by a licensed health care provider, or have a certificate to practice such as Certified Nurse Midwives, Certified Registered Nurse Anesthetists, Certified Respiratory Therapy Technicians, Clinical Nurse Specialists, Nutritionists, Pharmacists, Physician Assistants, Registered or Licensed Practical Nurses, and Registered Respiratory Therapists.

9. Section B – 7I (Physical Therapy & Speech-Language Services)
Why not combine this in "7C" with Occupational Therapy? They are all combined in the Summary of Benefits and Evidence of Coverage.

CMS RESPONSE: CMS Policy has indicated this cost sharing needs to be reviewed separately and is therefore in a different sub-section in Service Category 7 (Health Care Professional Services).

10. Section B – 8B (Outpatient Diagnostic & Therapeutic Radiological Services)
Last box, titled "Is a referral required…": Need to rearrange the services to reflect "X-Ray Services" first. This is consistent with the order of the PBP questions.

CMS RESPONSE: CMS has determined this modification cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

11. Section B – 8B (Outpatient Diagnostic & Therapeutic Radiological Services)
Due to the advanced diagnostic radiological technology capabilities now available, with higher cost requirements; can additional options/boxes be added to segment these out (i.e. MRI / PET / CT / etc.)? This will allow clearer segmentation of cost sharing for the beneficiary.

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

12. Section B - 9A (Outpatient Hospital)
Should this title be expanded to be "Outpatient Hospital Surgery"?

CMS RESPONSE: CMS has determined this change cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

13. Section B – 10 A (Ambulance)
Need to add the type of transportation: one-way or round trip. (Refer to 10B)

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

14. Section B – 10 A (Ambulance)
Add "non-emergency" in referral-required option.

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

15. Section 13 C – Other Service Category
What types of services would qualify to fall into these categories? We have had several denied in the past. Make the "Enter name of Service" required vs. optional. Desk review can then validate adequacy of service description.

CMS RESPONSE: As in indicated in the 30-day PRA package for CMS R -262, Section 13 C will now become the data entry for "Part C OTC Drugs." If a user is unsure what is an acceptable benefit offering, please contact your regional Account Manager or your Division of Benefits contact for further clarification. For the "other" service categories, the "enter name of service" is an optional field because organizations are not required to offer these additional services.

16. Section B - Throughout
PBP needs to "consistently" have minimum and maximum cost sharing capabilities. Some segments only allow for one cost-sharing value; not a range.

CMS RESPONSE: CMS Policy has determined that the minimum to maximum cost share range only applies to certain categories. CMS may consider expanding the minimum to maximum cost share ranges to addition service categories in a future release of the PBP software.

17. Section B – 14D (PAP/Pelvic Exams), 14E (Prostate Screening), and 14H (Mammography)
Where/why would you have a situation with a PAP/Pelvic, Prostate Screening, or Mammography requiring separate cost sharing at a separate facility?

CMS RESPONSE: This question is no longer applicable as the facility fee question will be removed from the PBP software for CY 2010.

18. Section C - OON
Are you required to provide offsetting out-of-network benefits for all in-network benefits?

CMS RESPONSE: For PPO plan types, CMS policy requires all services covered in-network must be covered out-of-network. Edit rules in the PBP software ensure that this requirement is met.

19. Section C - OON – Inpatient and V/T – Inpatient – US
First box –To clarify, insert "inpatient psychiatric".

CMS RESPONSE: CMS has determined this additional data cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

20. Section B – 4A (Emergency)
For worldwide emergency coverage, the PBP does not include a selection for days/hours within which admission must occur for waiver of copay. Need to add this as a selection criterion in the PBP.

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

21.) Section B – 4B (Urgently needed care)
The PBP does not currently collect worldwide urgent coverage. This question needs to be asked in the PBP.

CMS RESPONSE: Urgent Worldwide coverage is collected in B – 4A. You will see an on-screen label that indicates the worldwide supplemental benefit "includes Worldwide coverage or urgent/emergent and post-stabilization care."

22. Section B – 18 A (Hearing Aids)
Because we cover hearing aids and routine hearing exams differently, we would like CMS to split out the hearing aid coverage and routine hearing exam coverage.

CMS RESPONSE: CMS has determined this additional data entry cannot be accommodated for CY2010. CMS will consider this suggestion for a future release of the PBP software.

23. Section B – 10B (Transportation)
The PBP needs to support the selection of one-way trips

CMS RESPONSE: The transportation section (10B – base 1) currently supports the data entry of "One-way," "Round Trip," "Days," or "Other, Describe" as possible transportation types.

24. Rx Section – General Screen II
Why is the question "Are there any drugs on your formulary for which access is limited" asked in the PBP. CMS mandated we answer this question "Yes" for CY 2009.

CMS RESPONSE: The Limited Access indicator is independent of the review for drugs that are required to be on all Part D formularies. As such, there could be a situation in which a Part D sponsor's formulary does not contain any of the drugs that must be indicated as requiring a limited access indicator. In this example, a sponsor would need to have the capability to indicate a "No" in the PBP.

25. Rx Screens – General
Regarding the Medicare Prescription Drugs Section screens, there is one field where the explanation (located in the box that appears under this question) is incomplete: "Out-of-Network cost sharing structure for this plan". It reads: "*If a plan chooses this option and does not utilize either a differential in cost sharing or a differential in days supply for out of network coverage, " NOTE: This appears on the Deductible and Pre-ICL screens.

CMS RESPONSE: These are screen mock-ups, not the final screen designs. The on-screen label will be displayed as follows when the software is released in April 2009:

If a plan chooses this option and does not utilize either a differential in cost sharing or a differential in days supply for out of network coverage, CMS' expectation is that the plan is monitoring for appropriate out of network use with either a post authorization process or alternative review tool.

26. Section B – 14B (Immunization)
There is the statement "Indicate whether a separate office visit cost share applies for services." Plans have the choice to check Yes, No or Sometimes.

When indicating whether a separate office visit cost share applies for services, plans have the choice to check Yes, No or Sometimes. During the 2009 PBP data entry, we checked "Yes." However, during the desk review of our plans, the reviewer required us to check Sometimes or No, stating that "Yes" was not an option. The answers were changed to "Sometimes" and the plans were re-uploaded. The reason given for the required change was that plans may only charge a separate office visit cost share if other services aside from the immunizations are provided. Otherwise the purpose of the visit is for the immunizations (Flu/Pneumococcal) and no cost sharing can be charged for those.

CMS RESPONSE: CMS will strive to provide more complete communication and policy guidelines and what is acceptable when completing the PBP data entry.

Formulary Comments

1. Formulary File Record Layout – RxCUI
The change to replace the NDC with the RxNorm-RxCUI field will create additional challenges to plans. If CMS' intent is to replace the NDC with RxNorm data in the Formulary Reference File, plans will need a crosswalk to cross reference to NDC accordingly. Without this, a significant amount of manual work will be required to quality check our formulary files.

The formulary file layout is based upon the removal of NDCs as the drug identifier on the file and the use of RxCUIs instead. Without additional information, it is difficult to envision all of the downstream processes that may be affected by the use of RxCUIs instead of representative NDCs, but we believe that this will have a significant impact on several areas include pricing files, the formulary look-up tool, and possibly customer services and print production. This will be a costly endeavor and require considerable retooling, and it is not clear what the benefits of this change are. We therefore request that CMS reconsider whether this change is necessary.

While RxNorm is a great concept, it is not in a state for daily usability by plans. It must be fully thought out, documented and serviced in order to be used on a daily basis. It must be mapped to internal systems. In order to do this it must be in a completed format with logic that can be integrated in a consistent and clear manner. We strongly disagree with using' RxNorm in 2010. We feel it must be postponed until there is a clear algorithm for use as well as a clear path for customer support.

Our recommendation is that tiering and UMs should be allowed to be differentiated at the strength level using a unique RxCUI. NDC and RxCUI crosswalk should be published. FRF file and file layout should be released earlier than a few weeks before submission to allow plans to make process changes for 2010 filing.

CMS RESPONSE: In the CY 2009 Call Letter, released in final draft on March 17, 2008, CMS notified Part D sponsors that we were considering the use of RxNorm RxCUIs for the purpose of HPMS formulary submission. We provided RxCUIs and RxNorm descriptions for proxy NDCs contained on the CY 2009 Formulary Reference File (FRF). CMS also indicated during 2008 NCPDP Workgroup meetings that we had not identified any technical reasons not to move towards RxCUIs for CY 2010. We believe that we have provided ample notice for Part D sponsors to prepare for the transition to RxNorm.

CMS recognizes several advantages associated with the transition to RxCUIs. The RxNorm nomenclature system normalizes the naming convention for drugs across several data sources. Since RxCUIs are generally much more stable than NDCs, CMS will be able to avoid situations in which an FRF proxy NDC becomes inactive or obsolete, which produces operational challenges for both CMS and Part D plan sponsors. In addition to these Part D advantages, the move to RxNorm complements HHS' overall efforts to promote adoption and utilization of interoperable electronic standards. RxNorm is named as a Health Information Technology Standards Panel (HITSP) standard for recording and exchanging data about clinical drugs for medication history and about brand name drugs for allergies.

We do not believe that this transition will have significant "downstream" effects on other CMS processes. While RxCUIs will be the code used for formulary submissions, CMS will provide a sample NDC for each RxCUI on the FRF. It is CMS' intent that Medicare Prescription Drug Plan Finder (MPDPF) pricing data submissions will be based on this

sample NDC, consistent with current practices. However, these sample NDCs will be refreshed on a regular basis to ensure even more current and accurate pricing information in MPDPF. CMS intends to release a draft CY 2010 FRF in January 2009. Part D sponsors will have the opportunity to review the file and submit addition/clarification requests well in advance of the April 2009 submission deadline. We do not believe that changing the HPMS formulary submission code from an 11-digit proxy NDC to a 6-digit RxCUI would have any impact on formulary look-up tools or customer service.

CMS continues to work with the National Library of Medicine (NLM) to refine the RxCUIs to ensure a seamless transition for CY 2010. We strongly believe that RxNorm is in a state of usability by CMS and Part D sponsors for HPMS formulary submissions. Their will be a sufficient amount of breadth and clinical distinction between the FRF RxCUIs to ensure that formulary coverage information, such as tiering and utilization management edits, will be accurately displayed.

2. Formulary File Record Layout – Quantity Limits
Under the new proposed approach, quantity limits will be normalized to a single field on the file, which is quantity per 31 days. We are concerned that a level of meaning is lost with this change in that it is far clearer to the member that he/she is limited to 90 units of a proton pump inhibitor in 365 days when it is shown as 90 per 365, instead of 7.64 with an implied time period of 31 days.

The changes to the removal of the Quantity-Limit-Days field, and the Quantity-Limit-Amount field representing 31 days will require plans to make a number of operational changes.

CMS provided the requirement for quantity limits be expressed as 31 days. Does this preclude plans from offering benefits other than 31 days (e.g. 34 days, 30 days)?

With the 31 day QL days, how should plans represent the quantity limit where the amount is per fill?

While standardizing all quantity limits to a 31 day supply will allow CMS to compare most quantity limits across plans, it will not allow enough information to be submitted in cases where the quantity limit cannot be accurately translated into a 31 day supply.

CMS RESPONSE: The Quantity Limits Days fields will be included in the CY 2010 Formulary File Record Layout, consistent with the current CY 2009 requirements.

3. Formulary File Record Layout – Step Therapy (ST) Type
The ST type field should repeat for each associated step therapy.

There may be situations when two drugs under a ST Group may have different step types.

CMS RESPONSE: The intention of the ST type field is to ensure that ST restrictions will not be applied to beneficiaries who are currently taking a drug within the six classes of clinical concern. The ST type will be moved back to the RxCUI level, consistent with the current CY 2009 requirements.

4. Prior Authorization (PA) Record Layout – Coverage Duration

The PA coverage duration field is too short to clearly state what the authorization limit is for each approved indication. An abbreviated authorization limit can be used but most patients will not be familiar with these abbreviations so it will be difficult to determine how long the drug will be approved for.

The field length is 100 characters. To clearly describe, it would be helpful to have a 300 character field limit

CMS RESPONSE: The proposed CY 2010 field length is consistent with the current CY 2009 requirements. CMS has analyzed the current PA submissions and has determined that the character length is sufficient.

5. PA Record Layout – PA Group Description

The prior authorization (PA) file layout is changing to that the PA group description will be eliminated (essentially replaced with the RxNorm CUI). This will require that the PA criteria be duplicated for each drug. This significantly increases the administrative burden on Part D sponsors in entering PA criteria. In light of these additional burdens without any clear benefits, we request that CMS reconsider these changes, and leave the method for describing PAs unchanged.

The changes proposed are removing PA Description, then using RxCUI on the PA file. This will mean every RxCUI will need to have the criteria repeated. The files are going to be too large and it will be difficult to maintain consistency when you have the same criteria for 25 RxCUIs.

The new proposed requirement with the criteria to be submitted (and duplicated) for each affected RXNorm-RXCUI field will drastically increase the plans' burden to conduct adequate quality assurance reviews in the time allotted where prior authorization criteria are combined for multiple drugs under one group description.

Use of RxNorm on PA record layout will cause a separation of policies and increases burden on the validation process.

The Prior Authorization Group Description greatly simplifies the submission of PA criteria, and helps produce a file that can be easily interpreted. Removing this field will result in plans submitting duplicate records of criteria. The current system allows for easier maintenance and review of PA criteria.

CMS RESPONSE: The PA Group Description field will be included in the CY 2010 Formulary and PA File Record Layouts, consistent with the current CY 2009 requirements.

6. Supplemental Files – Submission Deadline
Will the files be due in April or June?

CMS RESPONSE: The submission deadline will be in June 2009. The specific dates will be provided during formulary training sessions and in the HPMS Formulary Submission Module and Reports Technical 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.