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CENTER FOR **M**EDICARE

TO: Office of Management and Budget

FROM: Lori Robinson, Director
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DATE: December 8, 2015

SUBJECT: Response to CMS-R-262 60-Day PRA comments

CMS appreciates the comments provided on the Paperwork Reduction Act (PRA) package CMS-R-262, *Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP).* Our responses to the comments submitted are below.

Plan Benefit Package (PBP) and Summary of Benefits (SB) Comments

1. PBP Section Rx

Pages 7 and 8: what are the different options in the drop downs for Tier 5 or Tier 6?

CMS RESPONSE: As indicated in the 2017 Tiers labels chart, the different options for the optional tiers can be used as an excluded drug only tier or for other meaningful offerings, such as a $0 tier.

2. PBP Section Rx

Pages 12 and 13: Is the total inventory of options for Tier 5 or Tier 6 listed? Our common 5 Tier structure with Specialty on Tier 5 is missing.

CMS RESPONSE: As indicated in the 2017 Tiers labels chart, there are several tier options under the 5 tier module with the specialty tier being tier 5 (e.g., Tier model 5A, 5C, 5D, 5E, and 5F).

3. PBP Section Rx

I am unable to locate the following PDF - Appendix_C_CY2017_PBP_screenshots_Tier_Models.pdf

CMS RESPONSE: This document is included in the PRA package found at
https://www.cms.gov/Regulations-and-

. The name of the document is "508_2017 Tier Models_FINAL for PRA.PDF."

4. PBP Section Rx
Page 29: The deductible question: "Indicate each tier for which the deductible will NOT apply" is a double negative and leads to incorrect filing and causes confusion. Can this be changed to: "Indicate each tier for which the deductible WILL apply".

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

5. PBP Section Rx

The Medicare Rx - Tier Models have been updated to more closely reflect the industry standard tier structure design.
We believe the 6 tier option outlined on the model form should also provide the option (as seen with the 5 tier options) to offer a "Non-Preferred Drugs" tier versus only being able to offer a "Non-Preferred Brand" Tier.

CMS RESPONSE: Many of the 5 tier options include the Non-Preferred Drug tier and optional 6th tier. CMS believes this user can accomplish what they have described above with the proposed tier structures for CY2017.

6. Formulary

We would like to take this opportunity to suggest that for the 2017 BID submission, the timeframe for a 2017 FRF initial release and subsequent pre-bid deadline update be changed.
Although it is helpful to have an FRF update available for 2017 filing purposes prior to the final bid deadline - for the purposes of bid calculations - it would be better to have the FRF update file released at least three weeks before the final bid submission due date in June. Thank you for your consideration of this request.

CMS RESPONSE: CMS appreciates this feedback and will strive to make the 2017 updates available as soon as possible.

7. Formulary - Supplemental File

CMS will collect a new supplemental file containing RxCUIs for the drugs not available at an extended day's supply under the Part D plan's benefit.
We would suggest that if the plan chooses to restrict extended day supplies at a tier level (i.e. all drugs on the Specialty Tier are not available at an extended day supply) that the plan NOT be required to submit a supplemental file and instead be able to designate this in the PBP and HPMS formulary module as applicable to the entire tier.

CMS RESPONSE: This is the way the supplemental file will work for next year. A supplemental file is only needed if a plan chooses to restrict extended day supplies at a PARTIAL tier level. If the extended day supply is at a full tier level, a supplemental file will not need to be uploaded.

8. Formulary tier models

We recommend that CMS allow formularies the flexibility of having 7 tiers so that health plans would be able to provide members a chronic care tier, as well as a supplemental drug tier, if desired. The changes creates a challenge in case a plan wants to include a Supplemental Tier but already has a 6th tier for Select Care drugs.

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

9. PBP Section Rx

To minimize any disruption in service to our members and to better manage member satisfaction, we recommend that instead of using tier labels, plans be given the flexibility to place higher cost generics into higher tiers and use tier numbers instead when referring to drug placement in their formularies. An alternative to moving from tier labels to tier numbers will be to expand the brand tier labels to indicate if generics are also tiered there.
The use of tier labels can be confusing to members since it does not always indicate exactly the type of drugs included. For example, sometimes a generic drug could be in a tier that is named Preferred Brand. Then the tier name becomes confusing and disingenuous.

CMS RESPONSE: This comment is not related to the PBP or the Formulary labels. It is regarding the marketing approach of tiers to beneficiaries. CMS will consider these as part of future Part D marketing instructions/guidance.

10. PBP Section Rx

We recommend that CMS allow health plans to move the Select Care Drugs (tier 6) to tier 1 to be more consistent with the members' understanding that as the tier numbers go up in value, so does the associated cost-share with each tier.

The tier system is set up so that as the tier number rises, so does the member's costs. But, Select care drugs have low or generally no copays. Having Select care drugs as the highest tier is confusing for members.

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

11. Formulary – Submission file Drug Type Label

We recommend that CMS make the necessary correction in the formulary file record layout-Drug Type Label so that a submission error does not occur when a label that is no longer allowed is used.
We also have a comment related to the new formulary file requirement (RxCUI supplemental file). This requirement should clearly define whether prepackaged drugs or drugs not generally dispensed in extended supplies (e.g. antibiotics) should be included in this file. It is not clear from the definition

whether the intent is to identify all drugs not available for dispensing at a 90 day supply or if the file is to identify drugs the plan limits to 30 day supplies, if applicable.

This tier label was eliminated with the 2016 submission.

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

12. PBP – Appendix C Rx Screenshots

Old language "non-Preferred Generic" is reflected in the screenshots. Since CMS did not indicate that this tier label will be available in their 2017 Tier Labels & Hierarchy document, we recommend that CMS clarify that it was their intention to use the term "Non-Preferred Generics" in the screenshots included in Appendix C on (pgs. 6-6/68 of the supporting documentation.

CMS RESPONSE: CMS will update this terminology in the PBP for CY2017. We apologize for any confusion from the current screenshots, as they will be fixed before the final release of the software.

13. PBP - General

For Rx, PBP occasionally inadvertently erases daily copay amounts after exiting/validating. We request that CMS fix the Rx section in PBP so that daily copay amounts are saved when exiting/validating the software

CMS Response: CMS has reviewed this comment and will consider this enhancement for the next contract year. In some instances, the PBP purposefully clears out select data to ensure all necessary validations are performed.

14. PBP - General

The Plan Benefit Package (PBP) screens cannot be viewed in whole without having to scroll up/down/across. Because the screen does not display all the content at once when there is a large amount of data to be entered, there is difficulty viewing the whole page to review the data elements. We suggest the scroll feature be taken out to ensure better viewing of all data on the Plan Benefit Package (PBP) screens.

CMS RESPONSE: The zoom can be fixed on an individual user's computer. If the resolution is too big, the user can zoom out and will then not have to scroll using the PBP screens.

15. PBP – Section C

Section C, Out of Network (OON): Requires the user to manually create groups of benefits rather than matching the format in Section B. Due to the limit of groups in Section C and the need to include multiple service categories in groups, the OON benefits can look confusing when in the plan finder and Summary of Benefits. The manual grouping also increases the likelihood of data input errors. To avoid misrepresenting cost shares for benefits, we request that CMS enhance the Out of Network section to mirror Section B by having Section C broken out into each service category, numbers 1 through 20,

rather than requiring the user to manually group the service categories into a limited number of groups with the same cost sharing.

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

16. PBP – Plan Upload Screen

Screen is only large enough to display the first 3 numbers of the plan upload number. PBP Plan Upload screen isn't large enough to see all data in this function and does not allow the user to enlarge it any further. This means that the user is not able to confirm/check plan upload numbers on this screen. To allow users to view the entire plan upload number on the PBP Plan upload screen, we request that CMS enlarge the screen.

CMS RESPONSE: The zoom can be fixed on an individual user's computer. If the resolution is too big, the user can zoom out and will then be able to see all numbers of the plan upload number.

17. PBP – General

Summary: User receives error indicating that Tier 1 has not been selected, even though it has been on screen Alternative – Tier Type and Cost Share Structure – Pre-ICL. The PBP software is producing an error even though the user has selected the item requested. This appears to be a bug in the system. We suggest that CMS revisit this piece of the software and address any bugs which may be causing this error to occur.

CMS RESPONSE: CMS will thoroughly test the PBP software and will address any bugs that are found in the software.

18. SB - Supplemental Gap

Summary of Benefits (SB) supplemental gap language is standardized and does not accurately reflect benefit design according to the PBP entries. Plans cannot clearly outline their benefit design since the gap language is standardized. To allow plans to outline their benefit design, we suggest the following sentence be used to replace the current narrative: "Under this plan, you may pay even less for the <brand/generic/brand and generic> drugs on the formulary."

CMS RESPONSE: The summary of benefits will not be generated out of the plan benefit package software in 2017, so this comment is not applicable. CMS will be issuing additional guidance about the summary of benefits for CY2017.

19. SB – Long Term Care

Summary of Benefits (SB) Long Term Care language is not variable according to the PBP entries. The language states as follows: "If you reside in a long-term care facility, you pay the same as at a retail pharmacy." Plans do not have the flexibility to tailor the language in the Summary of Benefits to match the benefit design filed by each plan. We request that CMS consider adjusting the SB Long Term Care language to be variable according to the PBP entry. Specifically, we suggest the following sentence be

reflected as follows: "If you reside in a long-term care facility, you pay the same as at a [preferred] [standard] retail pharmacy."

CMS RESPONSE: The summary of benefits will not be generated out of the plan benefit package software in 2017, so this comment is not applicable. CMS will be issuing additional guidance about the summary of benefits for CY2017.

20. Formulary – Submission File Record Layout

Tier labels for Tier 1 and Tier 2 appear to be reversed. The tier reversal is confusing for submission. We request that the tier labels for Tier 1 and Tier 2 be switched as a correction.

CMS RESPONSE: These labels will be fixed for the final CY2017 PBP.

21. PBP – Section Rx

Screenshots in Appendix C, PBP screenshots for section RX, pages 6-8 use old language of "Non-Preferred Generics." The "Non-Preferred Generics" language is no longer in use as of 2016 required CMS change. We request that the language in the file be updated to match the 2016 CMS required change.

CMS RESPONSE: CMS will update this terminology in the PBP for CY2017. We apologize for any confusion from the current screenshots, as they will be fixed before the final release of the software.

22. PBP – Section Rx:

With regards to tier labels, we would recommend that plans be given the ability to label the tiers based on what is in the tier. For example: Currently we have some generics in the following tiers, but are limited to the descriptions provided- Tier 3, preferred brand and Tier 4 nonpreferred brand. We believe accurate labels such as "Preferred Brand with some Generics" and "Non-Preferred Brand with some Generics" would better describe the contents of the tier to the member.

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

23. PBP – Section B

Section B, CY 2017 PBP Data Entry System Screens, #9a Outpatient Hospital Services - Base 1, Page 102 In the 2016 Call letter, page 130, CMS mentioned that they would either remove or disable 9a entirely and rename 9b. We were expecting to see this for 2017, but no changes appear to have been made. Please note, if 9a is removed or disabled, the Maximum Enrollee Out-of-Pocket Cost type would need to be updated in #9b ASC Services - Base 1 and #9c Outpatient Substance Abuse - Base 1.

CMS RESPONSE: After further consideration, CMS decided that no changes were needed to this section of the PBP for CY2017.

24. PBP – Section Rx

Section Rx, CY 2017 PBP Data Entry System Screens, Medicare Rx - Tier Model (when a tier includes 5 tiers), page 7 The formulary tiers refer to non-preferred generics, however, the 2016 call letter, page 156 tier labeling and composition told us that non-preferred generics had to be change to "generic" and it is not reflected in the documents we reviewed.

CMS RESPONSE: These tier labels will be fixed for the final CY2017 PBP.

25. PBP and Formulary – Tier labels

Currently, the tier label name corresponds to a type of drug, such a tier 1 = generic or tier 2 = preferred generic. Historically, drug types have implied the general cost of a drug. For example, generic would imply a low cost drug. Drug costs are shifting dramatically and it can make more sense to put a generic drug on a higher tier where traditionally a brand drug would placed. Similarly, there are brand drugs where it would make sense to place in the lower cost-share tiers that have typically been reserved for generics.

We recommend CMS discontinue using the drug type and solely move to a tier numbering structure to allow drug placement on a tier based purely on the drug cost and not the type of drug (generic or brand). This would allow more flexibility in mixing generic and brand drugs of similar cost into a tier rather than focusing on the type of drug in that tier. We feel this would make more sense to beneficiaries to explain the drugs that falls within a certain price range fall under a specific tier.

We recommend CMS update the PBP to reflect a tier numbering structure and discontinue the use of the drug type in the tier label name.

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

26. PBP – Section B

Section B, CY 2017 PBP Data Entry System Screens, #14c Eligible Supplemental Benefits as Defined in Chapter 4 - Base 1, Page 182 The enhanced benefit of Counseling Services needs to be clearly explained in the description of benefit at top of page.

CMS RESPONSE: CMS will work to issue clearer guidance on the enhanced benefit of counseling services.

27. PBP – Section B

Section B, CY 2017 PBP Data Entry System Screens, #3 Cardiac and Pulmonary Rehabilitation Services - Base 3, Page 50 CMS questioned the co-payments that were entered. We would recommend that CMS put in edits to limit the co-payments or coinsurance as they have with other categories. This would prevent plans from entering cost sharing amount higher than CMS expects.

CMS RESPONSE: CMS has reviewed this comment and will consider additional cost-share limitations for Cardiac and Pulmonary Rehabilitation Services in the future.

28. PBP – Section D

Section C, CY 2017 PBP Data Entry System Screens, Plan Deductible LPPO/RPPO Base 1, page 1. The statement regarding what must be included in all OON Medicare covered services for LPPO and RPPO (bottom left corner) we would like to recommend excluding ambulance services from the deductible since they are typically not within a plans network.

CMS RESPONSE: CMS has reviewed this comment and will consider additional cost-share limitations for Cardiac and Pulmonary Rehabilitation Services in the future.

29. Formulary - PA File Record Layout

Comment regarding the CY 2017 Prior Authorization File Record Layout: Please consider increasing the maximum field length in the "Coverage Duration" field to accommodate for the different length of therapy for novel Hepatitis C drugs (e.g., Harvoni, Sovaldi, etc.) that may vary depending on the past medical history, cirrhosis history, and genotype and requires at least 500 characters to describe.
Comment regarding the 2017 Tier Labels and Hierarchy: We support the proposed 2017 Tier Labels and Hierarchy changes to more closely reflect the industry standard tier structure design (specifically, provision of option F):
Option F:
Tier 1: Preferred Generic
Tier 2: Generic
Tier 3: Preferred Brand
Tier 4: Non-Preferred Drug
Tier 5: Specialty Tier
Tier 6: Optional*
*The optional 5th or 6th tier can be used as an excluded-drug-only tier or for other meaningful offerings such as a $0

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

30. PBP – Section B

Section B, CY 2017 PBP Data Entry System Screens, #7h Psychiatric Services - Base 3, Page 90. The screen reflects Occupational Therapy Services Notes, in the Psychiatric Services area, please update.

CMS RESPONSE: CMS will fix this error in the PBP screenshots. Thank you for bringing it to our attention.

31. PBP – Section B

Section D, CY 2017 PBP Data Entry System Screens, Plan Premium/Rebate Reduction, Pg 19 Typically we store premium estimates only in the BPT. Is this new screen, supposed to mirror the BPT entry? Will we have to go back in after the benchmarks are released to update this field? For zero premium plans do you enter zero? Since this is for the PBP only (Medicare A/B) where does the Part D portion get entered to make it whole?

CMS RESPONSE: These screens are only available to cost plans, and they do not fill out the MA Bid Pricing Tool. Since they do not fill out a BPT, these plan types fill this in the PBP.

32. PBP – Section Rx

Section Rx, CY 2017 PBP Data Entry System Screens, Alternative - Retail Pharmacy Location Supply - Pre-ICL, page 34. The formulary tier labels appear to be set; however, on this screen and others, it appears as though the plan may enter a tier description. Will these descriptions override the formulary tier labels? If not, what is the purpose of plans inputting their own descriptions?

CMS RESPONSE: There is no tier description that a plan may enter. The formulary tier labels are standardized and what will appear on all screens.

33. PBP and Formulary – Tier Labels

Regarding PBP Section Rx, Item 4, the Medicare Rx-Tier Models have been updated to more closely reflect the industry standard tier structure design:

We support the change regarding 2017 new options for 3-Tier, 4-Tier, and 5-Tier structures that one tier is labeled "Non-Preferred Drug" because this change conveys that the tier will contain both brands and generics. However, the lower tiers in these options retain the brand and generic tier labels, which may contribute to the common misconception that a tier labeled "Brand" contains only brands and a tier labeled "Generic" contains only generics. We encourage CMS to offer tier labeling options that do not depend on "brand" or "generic" as part of the label and urge the recognition that both brands and generics can legitimately be placed on all tiers.

Industry is seeing significant prices increases for generics; the generic is not always cheaper than the brand; and we expect this trend to continue. Plans need to balance the drug spend among tiers to meet bid requirements and constraints. As more brands move to generic status, even more generics will need to move to higher tiers in order for plans to remain compliant with bid guidance. Industry is not seeing the generic prices falling after generic launches, as we have seen historically. These increases will further lead to retiering of some generics.

Based on cost, marketplace trends, and bid guidance, distinctions between brands and generics are blurring. For all these reasons, we believe low net cost to the member along with clinical appropriateness should be guiding principles of formulary tiering, rather than the placement of generics or brands within specific tiers.

We also encourage CMS to consider changing the labeling of the Specialty tier to better describe them as high cost drugs, as many drugs that meet the CMS-specified financial threshold for placement in this tier are not specialty medications.

Additional tier labeling options enables plans to clearly communicate the cost-sharing associated with each tier while avoiding misconceptions regarding the mix of drug type composition on each tier. Members and providers will be able to better identify lower cost or preferred drugs through use of tier labels that clearly identify lower cost-sharing options rather than drug type labels.

Here are three potential recommendations for five-tier formulary structure:

(1) Provide an option that removes all tier labels except for the Specialty Tier, which we recommend be renamed the High Cost Tier. All other tiers would be referenced using only the tier number corresponding to each cost-sharing level. As generics & brands can be placed on any tier, including them in the label can be confusing and lacks transparency. Here is the example the five-tier formulary for this scenario.
Tier 1
Tier 2
Tier 3
Tier 4
Tier 5 - High Cost Tier

(2) Provide an option removing references to generics and brands from the tier labels and replacing them with labeling that better corresponds to the cost sharing the member will experience. Here is the example the five-tier formulary for this scenario.
Tier 1: Lowest Cost Sharing Preferred Drugs
Tier 2: Low Cost Sharing Preferred Drugs
Tier 3: Middle Cost Sharing Preferred Drugs
Tier 4: Higher Cost Sharing Non-Preferred Drugs
Tier 5: High Cost Tier

(3) If CMS maintain references to generics and brands, we recommend that tier labeling options be provided that include both generics and brands in each label, as appropriate. This would enable plans to clearly describe the drug types included on each tier. Here is the example the five-tier formulary for this scenario.
Tier 1: Value Generics & Value Brands
Tier 2: Preferred Generics & Select Preferred Brands
Tier 3: Generics & Preferred Brands
Tier 4: Non-Preferred Generics &Non-Preferred Brands
Tier 5: High Cost Tier

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

34. Formulary – Supplemental formulary file (Extended Day Supply)

Regarding CY2017 Formulary Changes, item 1, CMS will collect a new supplemental file containing RxCUIs for the drugs not available for extended day's supply under Part D plan benefit. CMS has proposed a new supplemental file containing RxCUIs for drugs that are not available with an extended day supply. We do not believe that an additional supplemental file to identify these drugs at the formulary level is necessary, as the submitted Plan Benefit Package (PBP) for a plan already identifies drugs for a particular tier that are not available for an extended days supply. This information is also reflected in the Summary of Benefits and Evidence of Coverage as part of the plan design. Furthermore, submission of supplemental file updates during monthly formulary submission windows (e.g. additions due to new drugs added to formulary, removals due to drugs removed from the Formulary Reference File) would be duplicative of information already submitted on the formulary.

CMS RESPONSE: CMS has reviewed this comment and will consider the necessity of this file for the next contract year.

34. PBP

Although many changes described in the presented documents apply to the BID submission and the tools used, Commonwealth Care Alliance would like to take the opportunity and comment on the work that needs to be done with regard to PBP software for FIDE SNPs. As a FIDE SNP, we feel the immediate need is the ability for the PBP software to accept submission of Medicare & Medicaid covered benefits. The current structure of the PBP requires plans like ours to submit many hard copy changes in order for the Summary of Benefits (SB) to accurately reflect our benefit plan. The additional request for hard copy changes places an onerous burden on us and makes it more difficult for us to meet some of the CMS mailing timeframes. We encourage CMS to work with Medicaid and FIDE SNPs to develop an integrated software program for FIDE SNPs. Commonwealth Care Alliance feels the PBP software used by the Medicare-Medicaid Plans is a first step in developing this software. Additional work is required.

CMS RESPONSE: CMS has reviewed this comment and will consider this enhancement for the next contract year.

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

Thank you.