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

TO: OMB

FROM: Lori Robinson, Director
Division of Plan Data

DATE: December 28, 2007

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
This screen has a hard-code for the Plan to complete indicting if the plan is a Network Plan with the responses limited to yes or no. Can this be expanded to consider any Plans that would have a limited network and then an opportunity in the Notes Field to briefly define the limited network or have the hard-coded area in Section A, A-1 screen open up additional hard-codes if a Plan responded yes. This would offer the opportunity to define the limited network components. In the latter instance, this could then transfer that information to the Plan's Summary of Benefits in Section I of that document.

CMS RESPONSE: This hard-coded response is captured in the Basic Contract Management module in HPMS, and the data is transferred to the local Plan Benefit Package (PBP) software. For CY2009, we anticipate that there will be three different types of network indicators collected in contract management: Full Network, Partial Network, or No network. For those plans that are indicated as a Partial Network (which you have identified as a "limited network"), plans will have the ability in the PBP to indicate from a picklist which service categories are covered Out-of-Network. This change will provide plans the opportunity to show which service categories are networked benefits and which service categories do not have a network.

2. Section C - OON - General - Base 2 Screen
This screen has added category 8b3 - x-rays to the OON General Base 2, OON Group Base 1, Cost Share Reduction General Base 1, and Cost Share Reduction Group Base 1. Will, or can, the same consideration be made for a PSO Plan that has an out-of-network component. Also, Section C and D have several similar drop-down selections (maximum member out-of-pocket, in-network plan deductible, maximum plan coverage (all Section

D) and visitor travel (Section C)). Can category 8b3 - x-rays be extended to those selections?

CMS RESPONSE: Currently, PSO plan types do not have access to the Out-of-Network Screens in the PBP software. Rather, PSO plan types are only presented with the POS and V/T screens in Section C of the PBP. For CY2009, CMS policy has determined that the level of detail described in this comment is not necessary at this time. Your suggestion will be considered for a future release of the PBP software.

3.) In the 2008 PBP Software, the Inpatient Mental Health benefit does not appear on the Summary of Benefits when we select a non-Medicare cost share for Inpatient Hospital but select a Medicare cost share for Inpatient Mental Health benefit. CMS confirmed that this was a problem, but told us that it would not be addressed for the 2008 bids.

CMS RESPONSE: CMS did confirm that this was a software bug for CY2008. There was not sufficient time to fix this bug and include the modification in a CY2008 software patch. CMS will address this problem for CY2009.

4.) It would help to have a spreadsheet-like view of all plans and their benefits within the PBP software. Ideally, we would be able to change benefits from this view. The column headings would be contract and plan numbers and the row headings would be question numbers from the PBP. This would allow for comparison of similar benefits across plans and would aid in accuracy and consistency.

CMS RESPONSE: CMS currently has PBP features in place to help with consistency and accuracy throughout the PBP. PBP users currently have the ability to copy all or only certain sections of the PBP across plans and contracts. PBP users also have the ability to view data reports to see the response to each question answered in the PBP. CMS has determined this additional report cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software.

5.) The PBP is asking for home infusion drug cost sharing in Section B-15 (Part B drugs) but doesn't display any cost sharing language in Section #29 of the SB (Prescription Drugs). We would like to know if this was intended or not.

CMS RESPONSE: Home Infusion sentences will be displayed for the new home infusion category with the final release of the PBP software.

6.) PBP Data entry/B-17A Eyewear: For plans that charge a coinsurance for Post cataract eyewear they must indicate "yes" to the question "is there an enrollee coinsurance." Once they indicate "yes" they then must indicate the coinsurance amount to the question "Indicate coinsurance percentage for Medicare covered benefits." Having to indicate "yes" to the coinsurance question also requires they indicate the amount of coinsurance for non-Medicare covered eyewear. For example, if a plan charges 20% for post-cataract eyewear, they indicate so in #17B-Base 4 but also have to indicate 100% for non-Medicare covered eyewear if they don't charge a coinsurance for non-Medicare covered

eyewear. This generates an SB sentence "100% of the cost for glasses, limited to one pair of glasses every two years." Somewhat misleading if a plan offers either a copay or maximum coverage amount for non-Medicare covered eyewear. This same problem comes up for plans that provide a Maximum Plan benefit coverage amount for post-cataract eyewear rather than a coinsurance or copayment for Medicare covered eyewear. The SB, in this scenario generates a sentence that reads "$0 copay for one pair of eyeglasses or contact lenses after each cataract surgery as well as up to 1 pair (s) of glasses every two years." Again, the resulting SB sentence appears to be somewhat misleading for plans that offer a Maximum Plan benefit coverage amount in lieu of coinsurance or copays. I think this could be resolved by separating out the post-cataract (Medicare covered) cost sharing questions in the PBP from other non-covered eyewear cost sharing. If a plan offers a Maximum Plan coverage amount for Medicare or non-Medicare covered eyewear, the copayment/coinsurance sentences in the SB should be suppressed. This same issue applies to Section #18B, hearing aides as well.

CMS RESPONSE: Data entry is being completed incorrectly in the above examples. If a plan covers eyewear in full, the plan user should indicate there is no coinsurance for eyewear. Also, if there is a maximum plan benefit coverage, the plan user does not need to indicate the cost sharing and should just enter the max plan benefit coverage amount. SB sentences will generate accordingly.

7.) PBP Data Entry Section B-9 Al Outpatient Hospital Services: This section of the PBP generates a lot of questions in terms of what types of services (cost sharing) should be reflected in this section For instance, the definition could be any medical services received as an outpatient in a hospital setting, which could include; specialist visits, cardio rehab, radiation therapy, MRIs, CATSCANS, lab work, outpatient surgeries etc. If this is the case you would be inclined to reflect a range of cost sharing encompassing the cost sharing for these various services. Having said this, there is some concern these same services are also called out in other sections of the PBP e.g., B-8, B-9, B-9B, B-7 etc. We would like to see more definitive guidance on what services should be called out under B-9A in the BID Submissions manual.

CMS RESPONSE: CMS will consider adding the information requested above in additional Bid Submission guidance.

8.) PBP Data Entry B-15: Medicare Part B RX drugs: Would like to see day supply added for Part B drugs in B- 15 of the PBP.

For Part B drugs, the, plan benefit may specify the number of days supply that will be provided in a single fill. Currently this screen does not allow PBP users to specify days supply. We recommend adding a field to allow inclusion of this feature of the benefit.

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.

9.) PBP Data Entry B-7C and 7i: physical, speech and occupational therapy; would like to see B-7C; physical and speech therapy combined in the PBP with B-7i occupational therapy.

CMS RESPONSE: CMS has determined that combining these two service categories cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software.

10.) PBP Data Entry1 B-14F: Colorectal Screening: Section #B-14F, by definition, includes a number of screenings e.g., flexible sigmoidoscopy as well as a colonoscopy. Would like to see more guidance in the BID Submission ManuaVPBP instructions as to what cost sharing should be included in this section in terms of what's considered diagnostic vs. preventive. If this section includes both flexible sigmoidoscopies as well as colonoscopies this could require a ranges of copays or coinsurance for these procedures depending on the procedure. In some cases the cost sharing for an "additional screening" may pertain to only one of the screenings and not to both but the SB sentence generated states "$- copay up to 1 additional screening without stating whether or not its for a flex sig or a colonoscopy. Would like to see colonoscopies called out separately from flexible sigmoidoscopies in the PBP or the elimination of this "additional screening" sentence.

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

11.) We ask that CMS improve the ability within the PBP to input a Part B premium reduction.

CMS RESPONSE: Per the CMS Office of the Actuary (OACT), the Part B premium reduction amount is entered in the Bid Pricing Tool (BPT). The Part B premium reduction amount is only entered in the PBP for those plan types that do not submit a Medicare Advantage BPT. CMS will not make any modifications to this process for CY2009.

12.) We suggest that for PPO plans the PBP should allow for differentiation of out-of-network benefit limits across things such as routine eye exams, dental or eyewear. In the past, it has been impossible to separate in and out-of-network to allow for different amounts. The amounts for out-of-network had to be totaled and entered into a comments field. A change to the PBP would streamline this activity for plans and allow for greater clarity.

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

13.) The “List of Changes” document indicates that the “Do you charge the Medicare coverage limit?” box was added to these screens (B-7c and B-7I). Since Occupational Therapy and Physical Therapy and Speech-language Services have benefit caps under original Medicare, the question is unclear. It appears that the question is intended to ask whether the plan applies the same caps for these benefits as Original Medicare.

CMS RESPONSE: The interpretation of this question is correct. CMS will provide supplemental guidance to clarify the question.

14.) Several types of services, such as radiology, radiation therapy and lab services can be performed in more than one setting (B-14F). Currently plans can list cost-sharing for these services when performed in a clinical setting. However, cost sharing for these same services may differ in the hospital outpatient setting, and it is not clear in Section B-9A how that difference should be noted. We recommend inclusion in the Bid Submission manual of instructions that indicate how plans should enter into the PBP differing cost sharing for such services when performed in the hospital outpatient setting.

CMS RESPONSE: CMS will consider including additional guidance on how to complete this data entry. Please note, however, that the Bid User Manual is technical in nature, so this guidance may be presented in a different format.

15.) The "List of Changes" document indicates that the label "Even if you do not offer enhance [sic] benefits, you must complete this section for your Medicare Covered Benefits" was added to this screen as a clarification for data entry because these are Medicare covered benefits (B-14 A, B-16B, B-17B, B-18A). It appears that label is intended to instruct that all plans must respond to the first question on this screen, "Do you offer any Mandatory or Optional Supplemental benefits?" even if no enhanced benefits arc offered. For clarity, **we** recommend that a note to this effect be added to the box containing the question and that the new label be eliminated.

CMS RESPONSE: CMS has determined that the label will remain as is. Data entry is required throughout the remaining screens in this particular PBP section, and the currently location of the label will instruct PBP users that additional data entry is required.

16.) There are different types of colorectal screening tests, including flexible sigmoidoscopy and colonoscopy, for which the cost sharing may differ. This section allows the PBP user to indicate whether additional screening tests are provided beyond those allowed under Medicare frequency limits, but there is no field that allows the plan sponsor to specify that cost sharing for the tests will differ based on the type of test. Therefore, a single cost-sharing amount may be inaccurately attributed to all types of covered colorectal screening tests. We recommend that PBP users be allowed to enter distinct cost sharing amounts for each of the additional types of colorectal screening tests they cover.

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

17.) Section B 20 – Outpatient Drugs: It is our understanding that last year Medicare cost plans were instructed to include in the notes section for Section B-20-Outpatient Drugs or Section B-13 Other, information regarding coverage of home infusion drugs. We recommend that CMS clarify the same instruction will apply for CY 2009.

CMS RESPONSE: For CY2009, the PBP will capture home infusion drugs in Section B-15 for MA-PD plan types and in Section B-20 for Cost Plans not offering the Medicare Part D benefit.

18.) Medicare Rx Section - This screen allows the user to check either "yes," or "no" in response to the question, "Does the deductible apply to all drug types?" However, some plans with an alternative benefit may choose to apply the deductible to specialty tier, brand, or generic drugs. We recommend that CMS modify the PBP to permit plan sponsors to indicate that the deductible applies to one or more of the following: brand, preferred brand, generic, preferred generic, and specialty tier.

CMS RESPONSE: The purpose of this question is to determine if there is a brand-only deductible. For CY2009, CMS has determined this additional data entry cannot be accommodated. CMS will consider this suggestion for a future release of the PBP software.

19.) Please also modify the current date/time stamps by category in the history report section to indicate when actual data entry is changed, rather than for entering and exiting the section.

CMS RESPONSE: For CY2009, CMS has determined that this date/time stamp change cannot be accommodated. CMS will consider this suggestion for a future release of the PBP software.

20.) Please add a button to the Base 1 screen for each category that references any routine or special instructions for the PBP entry of that item, e.g., particular ranges that CMS mandates that the Plans use for Urgent Care. Also reference where the category can be located in the Call letter and the Bid Submission Users Manual. Special instructions in the PBP tool would greatly reduce the number of calls to CMS for assistance with clarification and will reduce the number and types of Plan Corrections required for 2009.

CMS RESPONSE: CMS cannot accommodate this level of detailed instructions in the PBP for CY2009. CMS will include additional guidance in other CMS documentation, where appropriate.

21.) Section B: please add an option to choose a "Per Benefit Period" Deductible. For example, for Inpatient cost sharing, B1b only generates a yearly deductible in the SB language.

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

22.) 4. Please provide each MCO with a PBP database type file that can be used to import the current benefits into the new contract years PBP tool.

CMS RESPONSE: CMS has determined that an import file cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software. Please note that PBP users currently have the ability to copy plan benefits to multiple plans and across contract numbers.

23.) Please provide each MCO with the ability to produce a PBP database output file that includes all available fields in the PBP, empty or answered by each particular Plan, in a fixed format. Each output record would have the fields in the same place, regardless if they were input with benefits to be used for validation and proofing purposes. This kind of database would be invaluable to Plans in their efforts to quality control the data input.

CMS RESPONSE: For CY2009, CMS will allow PBP users the ability to generate an XML file containing the text of the question, the text of the possible answers (where applicable) or range of possible values, the text of the selected answer(s) or the value, and the data representation (e.g., text, byte string) in the PBP Access Database file. Plans will be able to access this as a PBP report.

24.) For B-7, please clarify if this question should actually state: "Do you apply the Medicare coverage limit" versus "Do you charge the Medicare coverage limit".

CMS RESPONSE: The question will state: "Do you apply the Medicare coverage limit?"

25.) The submission PBP MDB and associated BPTs will keep the date/time stamp of when they were last modified. It would be beneficial to have an edit that asks if you want to save changes or have some type of "undo" feature.

CMS RESPONSE: CMS has determined an undo feature cannot be accommodated for CY2009. CMS will consider this suggestion for a future release of the PBP software.

26.) Please clarify if Home Infusion is a Part B or Part D expense, or both? If both, what distinguishes them?

CMS RESPONSE: For further clarification on Home Infusion Drug questions, please visit www.cms.hhs.gov to view reference documents, such as the document at: http://www.cms.hhs.gov/pharmacy/downloads/partsbdcoverageissues.pdf

27.) For 800 series plans we file an Original Medicare equivalent. This year was rather challenging on PPO side trying to make everything “look like” Original Medicare. I would suggest an option for 800 series plans that would start with the question: "Are you filing an Original Medicare equivalent?" yes or no. If yes, no other data entry is required. For PPO plans there would be the same question for Out-of-Network coverage.

CMS RESPONSE: CMS has determined that this feature cannot be accommodated for CY2009. Please note plans have the ability to copy plan benefits to other plans and across contracts. CMS will consider this suggestion for a future release of the PBP software.

28.) **Prior-Authorization-YN field**: 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?

CMS RESPONSE: This will be addressed in the CY2009 Technical User Manual.

29.) **Step-Therapy-YN 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 Croup. How should plans set the value of this field in this situation?

CMS RESPONSE: This will be addressed in the CY2009 Technical User Manual.

30.) **Step-Therapy-YN field:** 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 Croups, then both groups must set all member NDCs on the formulary to either "Step therapy applies" or "Step therapy applies to new starts only".

CMS RESPONSE: This will be addressed in the CY2009 Technical User Manual.

31.) **Step-Therapy-YN field:** 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?

CMS RESPONSE: This will be addressed in the CY2009 Technical User Manual.

32.) **Prior-Authorization-YN 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?

CMS RESPONSE: Changes in the Prior Authorization Type that result in a more restrictive offering to beneficiaries will be viewed as negative changes.

33.) **Step-Therapy-YN field:** How will CMS handle changes in this field in subsequent formulary submissions?

CMS RESPONSE: Changes in the Step Therapy Type that result in a more restrictive offering to beneficiaries will be viewed as negative changes.

34.) **OTC file:** 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

CMS RESPONSE: We are aware of this concern. Guidance for this will be provided in the CY 2009 Formulary Technical Manual.

35.) **OTC file:** Is a single representative NDC expected for each product / strength / dosage form 1 route covered, or are ALL potentially covered NDCs expected to be listed, including repackager NDCs.

CMS RESPONSE: We are aware of this concern. Guidance for this will be provided in the CY 2009 Formulary Technical Manual.

36.) **Excluded drug 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?

CMS RESPONSE: We are aware of this concern. Guidance for this will be provided in the CY 2009 Formulary Technical Manual

37.) 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?

CMS RESPONSE: We are aware of this concern. Guidance for this will be provided in the CY 2009 Formulary Technical Manual.

38.) 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?

CMS RESPONSE: Guidance on the identification and listing of the limited access drugs was given in CY 2008 call letter.

39.) 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?

CMS RESPONSE: Commenter does not understand what the excluded drug file is. This file is in reference to an enhanced alternative plans offering of excluded drugs as part of their supplemental benefit package. See the prescription drug benefit manual, chapter 6 section 20.1 excluded categories. All excluded products that the enhanced alternative plan is offering as supplemental coverage should be listed.

40.) 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?

CMS RESPONSE: Commenter does not understand what the excluded drug file is. Each enhanced alternative plan will determine on which tier their specific excluded drugs reside. Each enhanced alternative plan will submit a separate excluded drug flat file. Excluded drugs are not on the formulary reference file.

41.) Will plans be required to update this file as products are added to I deleted from the Formulary Reference File during the plan year?

CMS RESPONSE: Commenter does not understand what the excluded drug file is. These products will not be added to/deleted from the formulary reference file. Excluded drugs are not on the formulary reference file.

42.) Release of PBP Software: We request that CMS release the final PBP software before April and reduce the frequency of software patches. The frequency of software patches and their late releases has caused re-uploads of benefit filings and has an adverse downstream impact on plan timeframes for delivery of Annual Notice Of Change (ANOC) materials. An earlier release would allow organizations with a large number of benefit plans additional time to ensure the accuracy of the data entry and a reduction in patches will improve quality and eliminate rework.

CMS RESPONSE: Given the complexity of the software and the time required to design, develop, test, and implement the necessary software modifications, CMS cannot release the PBP software earlier than the April timeframe. In addition, CMS recognizes the difficulties placed on plans by late-breaking software patches. As a result, CMS is actively working to reduce the number of software patches for CY2009.

43.) We recommend CMS update the software or provide a tool that will map data fields from the prior year's data base format to the current year's data base format, including fields that have been eliminated. This would allow plans to improve quality and timeliness of data entry by allowing them to focus on new and changed fields, simplifying the quality control process.

CMS RESPONSE: CMS has determined that the proposed solution cannot be accommodated for CY2009. Please note that the list of CY2009 changes provided during alpha and beta PBP testing does address fields that have been modified or added for CY2009. CMS will consider this suggestion for a future release of the PBP software.

44.) Appendix C, PBP Screen Shots, Section b, p. 62, 81; #7c Occupational Therapy-Base 1 and 71 --Question--"Do you charge the Medicare coverage limit?": CMS has therapy caps in place for these, if a plan answers no, they don't charge the cap limit, there are no additional follow up questions. Since it appears the response to the question has no impact on the SB, please clarify what purpose the question serves.

CMS RESPONSE: CMS has determined the need for this question for the purposes of the Summary of Benefits (SB). This question will have an impact on the SB in CY2009.

45.) Appendix C, PBP Screen Shots, Section b, 9a and 9b, p 91, et al.: We Recommend differentiating between outpatient and surgery coinsurance and co-payments if the SB would also be re-worded to reflect the differences. For plans that differentiate between the two, this would eliminate the need to put ranges in the notes and provide greater clarity to the beneficiary regarding their co-payments and coinsurance for each type of service. For example: After the sentence "Is there an Enrollee Co-payment"? Add these sentences under the respective sections for coinsurance or co-payment: What is the coinsurance for outpatient hospital visit for surgery and/or observation? What is the co-payment for outpatient hospital visit for surgery and/or (observation? What is the coinsurance for other outpatient services? What is the co-payment for other outpatient services?

CMS RESPONSE: CMS has determined that this level of detail cannot be accommodated at this time. This suggestion will be considered for a future release of the PBP software.

46.) Appendix C, PBP Screen Shots, Section c, pp 32-50, Visitors/Travelers programs: We recommend updating the software to eliminate manual data entry for plans which offer the same benefits for the Visitor/Traveler benefits as in network benefits. For example, after answering the initial question "Do you offer a Visitor/Travel program" on page 32 and the initial question on page 33 "Do you offer a US Visitor Travel program?" we recommend adding the question, "Are benefits the same as in network?" Y/N. If "yes", then the software could auto fill all of the subsequent questions or read the information from Sect. B. This would eliminate errors resulting from manual data entry. We also recommend having similar logic in the deluxe rider section.

CMS RESPONSE: CMS has determined that this level of detail cannot be accommodated at this time. This suggestion will be considered for a future release of the PBP software.

47.) Expansion of the editing software to validate data fields prior to plan submission to CMS will improve data accuracy and significantly reduce the number of plans that need

to be resubmitted for correction during the re-bid process. The resulting reduction in plan corrections will save time and resources for both plans and CMS.

CMS RESPONSE: CMS enhances the validation capabilities of the PBP software each year and will continue to do so. Please refer to the list of CY2009 changes to see where validation has been added for the upcoming contract year.

48.) Standardizing column names and reducing the number of columns in the data bases by changing to a relational database structure would improve the quality of the databases by reducing keying activity and improving data consistency. The data dictionary would then be simplified when comparing values across benefits.

CMS RESPONSE: HPMS utilizes a relational database to store the benefits data collected in the PBP software. From the end user perspective, it should not matter how the data is stored in the PBP software database. This comment suggests that the user is attempting to modify the PBP database via the backend rather than by entering data through the user interface screens. The PBP software is not designed to accommodate backend data manipulation.

49.) We recommend CMS take steps to improve Benefit Bit Representation. Currently, when a new benefit is added at the 29th place, then the business rules must be changed for the benefits from the 29th to the 45th place. One modification then results in 16 modifications. One option is to add new benefits in the last place where it would not disturb other benefits. Another option would be to move toward a relational database.

CMS RESPONSE: HPMS utilizes a relational database to store the benefits data collected in the PBP software. From the end user perspective, it should not matter how the data is stored in the PBP software database. This comment suggests that the user is attempting to modify the PBP database via the backend rather than by entering data through the user interface screens. The PBP software is not designed to accommodate backend data manipulation.

50.) Currently, medical and Rx premiums are entered into HPMS and not into the PBP software, causing plans to use other methods to re-key the data. If these premiums were pushed down through the PBP software (similar to legal entity and plan type), dual entry would be eliminated and communication of accurate premiums to beneficiaries would be streamlined.

CMS RESPONSE: This comment contains incorrect information. The medical and Rx premiums are not entered into HPMS. Rather, these data are determined based on data entered into the Bid Pricing Tool (BPT), and some data, such as the Part D premiums, are not calculated and released until August, whereas the PBP is due in June. As a result, these data are not known in time to be entered into the PBP software.

51.) Appendix C, PBP Screen Shots, Section Rx, p. 2: When selecting "yes" to the added question "Does the plan provide Part D home infusion drugs as a supplemental benefit

under Part C?" a note comes up that information will transfer into Sect. C as of the June date. Nothing transferred over when selecting "yes." Will there be something printing over to the Summary of Benefits-(SB) and if so, what?

CMS RESPONSE: The note on the PBP screen refers to the formulary file submission date and is a reminder to PBP users that a supplemental formulary file must be submitted if they provide Part D home infusion drugs as a supplemental benefit. Please refer to the Summary of Benefits crosswalk to see which new SB sentences will be generated for CY2009.

52.) Appendix C, PBP Screen shots, Section b: For out of network benefits, plans currently cannot list the number of days for Skilled Nursing Facilities. We recommend adding an option for doing so. For example, as allowed on the inpatient hospital acute screens, ppl-14.

CMS RESPONSE: Please refer to the 30-day PRA package. For CY2009, CMS will allow detailed data entry of out-of-network SNF benefits.

53.) Appendix C, PBP Screen Shots, Section b, pp 2, 6, 16, 20, 31, 34: For PBP categories la, lb and 2, one of the questions asks if the fee for service cost share will apply. Selecting the option that cost sharing is the same as fee for service does not allow for input of periodicity. Periodicity is generally used to address cost share that is tied to per day limits and then subject to an Out Of Pocket (OOP) maximum. Without allowing for the input of that periodicity, the SBs for plans that have a cost share at the fee for service level do not reflect the limit on the number of days. We recommend CMS allow for entering the periodicity so that the SB reflects consistent information to the member.

CMS RESPONSE: For CY2009, CMS has determined that this level of detail cannot be accommodated at this time. This suggestion will be considered for a future release of the PBP software.

54.) **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?

CMS RESPONSE: Guidance for this will be provided in the CY 2009 Formulary Technical Manual.

55.) **Home Infusion Drug File:** 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?

CMS RESPONSE: To indicate on a plan by plan basis whether these drugs are covered under the Part D benefit or the Part C benefit.

56.) **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?

CMS RESPONSE: Guidance for this will be provided in the CY 2009 Formulary Technical Manual

57.) **OTC Drug 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. 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?

CMS RESPONSE: Guidance for this will be provided in the CY 2009 Formulary Technical Manual

58.) **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?

CMS RESPONSE: Guidance for this will be provided in the CY 2009 Formulary Technical Manual

59.) 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-Part D co-pay that a plan has members pay for these drugs. This non-part d co-pay 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?

CMS RESPONSE: Commenter does not understand what the excluded drug file is.

60.) **Excluded drug and OTC files:** The new files for excluded drugs and OTCs suggest use of a NDC versus a proxy NDC. , Would you please confirm the following: Will CMS provide a reference proxy NDC list for excluded and OTC drugs?

CMS RESPONSE: Guidance for this will be provided in the CY 2009 Formulary Technical Manual.

61.) If no, does CMS expect all detailed NDCs to be included in these files, or a plan-defined "reference" NDC for these files? 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? Does CMS require the Brand Name or Generic Name to be reported on the excluded drugs and over the counter drugs files?

CMS RESPONSE: Guidance for this will be provided in the CY 2009 Formulary Technical Manual

62.) **Home Infusion File:** Will CMS allow plans to add and remove drugs from HI drugs list after the initial submittal? 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 ASClls? If not, then how will plans document the negative change that will appear to have taken place in their formulary ASCII file?

CMS RESPONSE: Guidance for this will be provided in the CY 2009 Formulary Technical Manual.

63.) **Prior-Authorization-YN field:** There is no designated value to enter for prior authorization for drugs that require both a Part B/Part D determination and a clinical review (e.g., Procrit). Please clarify if a value of 1 should be entered or if there is a different value that should be entered.

CMS RESPONSE: This will be addressed in the CY2009 Technical User Manual.

64.) **Step-Therapy-YN field:** 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.

CMS RESPONSE: This will be addressed in the CY2009 Technical 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.