DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

TO: Office of Management and Budget

FROM: Lori Robinson, Director
Division of Plan Data
Medicare Drug Benefit and C & D Data Group
Center for Medicare

DATE: December 4, 2017

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.

CMS received thirty-one comments from three organization. In summary, many of the comments that were received were not being changed as part of this PRA package, and further some were even not part of the modules we were requesting comment on. For those that were part of the package, or for the modules in the purview of the package there were either no, or minor changes to burden. Overall, CMS has determined there will be no change to the burden estimate that was previously estimated for the package. Responses to the comments are below.

Plan Benefit Package (PBP) and Formulary Comments

1.) PBP Notes- CMS is directing plans to put multiple benefits into one service category. We use paragraphs to separate the benefits. When the PBP reports are created, the formatting in the PBP software is not carried over. If there are two paragraphs for two different benefits in one PBP note section, the two paragraphs become one paragraph in the PBP report. When we use the PBP report during quality check, it is difficult to see that there are two different benefit PBP notes. It would make it easier to read if the format stays the same as entered into the PBP software.

Response: CMS will be fixing this report display with the release of the CY2019 PBP software.
CMS Action: This change will be made to the PBP software for CY2019. It will have a small reduction on burden.

2.) PBP software to run compares-We appreciate the compare report and Medicare Plan Finder on HPMS. We recommend to have these reports in the PBP software as well. It would be useful to run compares in the PBP software without having to upload the bids onto HPMS. This is

especially crucial during the PBP review since we can only resubmit once when the gates are reopened. The compare report can be a useful tool to see the differences prior to resubmitting the bids.

Response: This comment is outside of the purview of this PRA package. The Medicare Plan Finder (MPF) preview report that displays in the Health Plan Management System (HPMS) is developed completely separately from the PBP. This report is developed on a different schedule and cannot be incorporated into the PBP software.
CMS Action: No action is required. There is no impact to burden estimates.

3.) PBP Reports-We appreciate the ability to save the report into excel format and would like the ability to save in PDF format as well.

Response: Users can export the report in excel and save the PBP reports in whatever format is preferred. The PDF formatting is not 508 compliant and was required to be removed.
CMS Action: No action is required. There is no impact to burden estimates.

4.) Rx Section in PBP software versus PBP Report-When we use the PBP report for quality check, it is quite difficult to follow when we compare it with what we entered into the PBP software. Could there be an option to print the PBP report in the same order as the PBP data entry versus tier 1, tier 2, tier 3, tier 4, and tier 5?

Response: CMS designed this report in this manner based on user feedback. End-users initially indicated that this was the preferred layout. CMS believe it would be incredibly confusing to follow the exact same order of the screens as the screen layout is different than the report display. CMS will look in the future to determine what changes may be made to the report to make it more user friendly.
CMS Action: No action is required. There is no impact to burden estimates.

5.) Copy feature-The copy feature did not work correctly for us at certain times. We would try to copy a category from one PBP to a few other PBPs. As we review the compare reports in HPMS, we would find that some PBP notes were not copied over.

Response: CMS and the development contractor will test to ensure all copy functionality is working. Please note, only applicable, overlapping sections in the plan benefit package (PBP) will copy between plans.
CMS Action: CMS and the development contractor will test to ensure this bug is fixed. There is no impact to burden estimates.

6.) EGWPs-We appreciate the option of selecting standard bid for EGWPs. However, we recommend that standard bid options have the ability to make changes to the data field.

Response: The standard bid option does allow organizations to modify the authorization and referral requirements. CMS contends that any further modifications to a standard bid would no longer make the bid fit the “standard bid” definition.
CMS Action: No action is required. There is no impact to burden estimates.

7.) Skilled Nursing Facilities-We were hoping to see a change with the enhancement to how the cost-sharing in this benefit category would display. Our SNF benefit is structured as "per day" vs. per benefit period or stay. As such, when reviewing the Medicare Plan Finder (MPF) summary, the cost-sharing is displayed as "for days 21 through 100" when it should state "<X> per day for days 21 through 100". Without the "per day" clarification, it is extremely misleading on the MPF. We strongly recommend CMS incorporate the "per day" language in this benefit category as part of the enhancement for transparency and accuracy.

Response: While this comment is outside of the purview of this PRA package, CMS can confirm that we will be making this fix in the Medicare Plan Finder (MPF) summary report.
CMS Action: No action is required. There is no impact to burden estimates.

8.) Inpatient Health and Mental Health Services-This benefit is currently displayed as "per stay" on the MPF and in the MPF summary report. For plans that charge a cost-sharing "per day", it is not being accurately reflected. Question: We are concerned that by leaving it as is and not clarifying that the cost-sharing is applied "per day," it is misleading on the MPF. We strongly recommend CMS incorporate the "per day" language in this benefit category as part of the enhancement for transparency and accuracy.

Response: While this comment is outside of the purview of this PRA package, CMS can confirm that we will be making this fix in the Medicare Plan Finder (MPF) summary report in HPMS.
CMS Action: No action is required. There is no impact to burden estimates.

9.) Medicare Plan Finder-The MPF was released late this year compared to previous years. We would appreciate it and it would be a tremendous help if it would be released earlier.

Response: Medicare Plan Finder (MPF) is outside of the scope of this PRA package. The MPF website is operated by a different Center in CMS. This commenter should direct their comment to the Office of Communication for consideration.
CMS Action: No action is required. There is no impact to burden estimates.

10.) Filing a range – We recommend that the benefits in each service category be split up to be more transparent for the beneficiaries. Instead of displaying a range on the MPF, the benefit and its cost-sharing from the service categories are listed. An example would be service category 9a-Outpatient Hospital Services. Instead of a range of $10-$200, MPF would list $10 for observation stays and $200 for surgery in an outpatient setting.

Response: This comment is outside of the scope of this PRA package. The MPF website is operated by a different Center in CMS. This commenter should direct their comment to the Office of Communication for consideration.
CMS Action: No action is required. There is no impact to burden estimates.

11.) INN and OON - We recommend that the INN and OON for each service category be in the same section instead of split out in Section B versus C. This would make it more efficient when entering both INN and OON benefits for each service category.

Response: The in-network and out-of-network screens were originally set-up in this manner due to industry comment and input. It was determined that many out-of-network services have

similar cost sharing (e.g., 40% for all OON services), which is why the OON screens have "groupings" for cost sharing. CMS will further explore this comment in CY2020.
CMS Action: No action required for CY2019. CMS will consider this enhancement for CY2020.

12.) PBP Review:

- We appreciate having one PBP reviewer for all contracts. This promotes consistency between benefits that were the same across contracts.
- The spreadsheet used during the PBP review can be difficult to follow.
- The reference category can be confusing. For example, 14c4. We were unsure what the 4 was referencing.
- We recommend the PBP review to be built into the PBP software. The PBP reviewer can make comments or notes in the PBP software. We can download the comments and see which screen or benefit the comments are correlated to and make the necessary changes. This would ensure the correct benefit is being changed or updated.
- We would appreciate it if there is coordination between the PBP and BPT reviewers when there are requests for us to resubmit the bid, so that the other reviewer is aware when a resubmission request is made and agrees that the timing and content of the request is appropriate.
- To the extent possible, PBP review should allow for sufficient time to review and certify the bid before the deadline, should benefit changes required as part of PBP review necessitate a change to the bid.
- If benefit changes are required and sufficient time is not given prior to the deadline, the deadline should be extended to the end of the next business day for quality assurance purposes.

Response: This comment is outside of the scope of this PRA package. The actual bid review process is conducted by several different centers within CMS. This commenter should direct their comment to the appropriate component for consideration. CMS also notes there is an annual bid submission lessons learned comment site where these types of comments should be submitted.
CMS Action: No action is required. There is no impact to burden estimates.

13.) Plan Benefit Package: Section B Inpatient Hospital-Acute Benefit Period (1a, Base 12) In this section, the question "What is your Inpatient Hospital-Acute benefit period?" is disabled when the benefit is filed as $0 per stay or $0 days 1 - X. Further, if a plan files additional days with a cost share, the question is still disabled. United requests that this question be enabled for all scenarios so it allows us to capture consistent data across all benefit set-ups.

Response: This change will be made in the CY2019 Plan benefit package. This will be reflected in the 30-day PRA package.
CMS Action: This change will be made to the PBP software for CY2019. It will have a small reduction on burden (organizations will not have to clarify benefit periods in the notes fields).

14.) Plan Benefit Package: Section B Inpatient Hospital Psychiatric Benefit Period (1b, Base 12) In this section, the question "What is your Inpatient Hospital Psychiatric benefit period?" is disabled when the benefit is filed as $0 per stay or $0 days 1 - X. Further, if a plan files additional days with a cost share, the question is still disabled. United requests that this question be enabled for all scenarios so it allows us to capture consistent data across all benefit set-ups.

Response: This change will be made in the CY2019 Plan Benefit Package software. This will be reflected in the 30-day PRA package.
CMS Action: This change will be made to the PBP software for CY2019. It will have a small reduction on burden (organizations will not have to clarify benefit periods in the notes fields).

15.) Plan Benefit Package: Section B Cost Sharing Fields for Remote Access Technologies (14c) In this section, the question, "Select the type of Remote Access Technologies offered (Select all that apply):" has been added to the Base 1 screen, with the option to select Web/Phone based technologies and/or a Nursing Hotline. However, there remains a single cost-sharing field for Remote Access Technologies. If CMS were to instead provide two separate cost sharing fields for Web/Phone based technologies and Nursing Hotline, MAOs would not need to file a cost share range in the service category. This would also eliminate the need for a note to explain which cost shares apply to each service. Therefore, United recommends that CMS provide two separate cost sharing fields for Web/Phone based technologies and Nursing Hotline.

Response: This change will be made in the CY2019 Plan benefit package. This will be reflected in the 30-day PRA package.
CMS Action: This change will be made to the PBP software for CY2019. It will have a small reduction on burden (organizations will be able to enter the appropriate cost-sharing in the data entry fields and not in the notes fields).

16.) Plan Benefit Package: Section B Supplemental Preventive and Comprehensive Dental (16a, 16b). The dental sub-categories used in the PBP software are different from, but similar to, the American Dental Association (ADA)-defined categories for dental services. This causes some confusion with MA plans when deciding which services should be filed to accurately align with the plan's benefit offering. In an effort to more accurately align dental services offered under Bid Categories 16a: Preventive and 16b: Comprehensive Dental with the actual bid filing, United requests that CMS modify the bid software for 2019 to be consistent with the ADA's code and category groupings.
For 16a, this would include:
•Diagnostic (D0100-D0999) – this category includes clinical oral evaluations and exams, xrays, oral radiology, and other diagnostic tests
•Preventive (D1000-D1999) – this category includes prophylaxis and routine teeth cleaning, fluoride, and other preventive maintenance services
For 16b, this would include each of the following ADA categories listed as separate benefit categories.
- Restorative (D2000-D2999)
- Endodontics (D3000-D3999)
- Periodontics (D4000-D4999)
- Prosthodontics - removable (D5000-D5899) and fixed (D6200-D6999)
- Maxillofacial Prosthetics (D5900-D5999)
- Implant Services (D6000-D6199)
- Oral & Maxillofacial Surgery (D7000-D7999)
- Orthodontics (D8000-D8999)
- Adjunctive General Services (D9000-D9999)

The category name and code ranges shown above correspond to the dental benefit categories and coding as established by the ADA, so it will be clear how the ADA groupings correspond to the PBP groupings. By detailing each of the ADA dental procedure categories in the bid under 16a and 16b, MA plans would be able to more clearly define the supplemental dental benefit to members in the evidence of coverage and prevent confusion at dental provider's offices. Prosthodontics fixed and removable would be combined into the same bid category.

Response: This comment was originally submitted to CMS over the summer. CMS reached out to this user several times over the summer to determine which categories in the PBP they felt needed to be modified, as all of these categories are currently captured throughout the dental section of the PBP software. CMS will further investigate this in CY2020, to ensure any modifications reflect this users intent.
CMS Action: No action required for CY2019. CMS will consider this enhancement for CY2020. There is no impact to burden

17.) Plan Benefit Package: Section B Note Fields

If a benefit has a cost share range, it is required to provide an accompanying note that explains the reasoning for the range. Currently, the PBP software allows the validation of a benefit entry that has a cost share range, but no accompanying note.
We believe that the following SNP type/plan type/benefits allow the user to exit validate without a note when a range is filled in:

- ISNP – All plan types - 7b, 14e, 16b, and 17a
- CSNP – All plan types - 7b, 14e, 16b, and 17a
- Non-SNP – All plan types - 7b, 14e, 16b, and 17a
- DSNP – HMOPOS, LPPO - 7b, 14e, 16b, and 17a
- DSNP – HMO - 7b, 14e, and 16b
- DSNP –RPPO - 7b, 16b, and 17a

Since a note is required when a range is filed, United believes it would be beneficial for the PBP software to prevent validation, or at least display a warning message (reminding the plan to include a note), before allowing validation.

Response: CMS previously received this comment. CMS cannot re-create this error and believes this error is created by a data feed issue on the plan's end.
CMS Action: No action required. There is no impact to burden.

18.) Plan Benefit Package: Section C Skilled Nursing Facility (SNF)

There do not seem to be validation rules applying to the day ranges for Skilled Nursing Facility in Section C of the PBP software. For example, the PBP software allows the user to exit and receive no validation

- End Day Interval 1 equals Begin Day Interval 2
- Begin Day Interval 2 equals 21, and End Day Interval 2 equals 20

There are rules for the day ranges in place for Inpatient Hospital Acute and Inpatient Psychiatric (OON and POS), so it seems that the same rules could also be used for SNF. We recommends that there be validation checks/rules for the day ranges for SNF similar to those for Inpatient Hospital Acute and Inpatient Psychiatric.

Response: This is a software defect and will be fixed with the CY2019 release.

CMS Action: This change will be made to the PBP software for CY2019. There is no impact on burden.

19.) Plan Benefit Package: Section C Number of Out-of-Network Groups

The current limit on the number of Out-of-Network groups in Section C has negatively impacted our ability to enter intended benefits in the cost sharing fields. When we reach the limit, we must file benefits in out-of-network that do not align with their intended cost share. A note is then added to explain which cost share is applicable to each benefit. United requests that CMS increase the limit of out-of-network groups, or eliminate the limit in the PBP software altogether. This would allow out-of-network plan benefits to be more accurately captured in the filing, reduce the number of filed notes, and provide better data for members in Medicare Plan Finder and the Medicare & You Handbook.

Response: CMS contends that 15 groupings for out-of-network benefits should be more than sufficient to capture out-of-network data. Organizations are also permitted to enter a cost-sharing range for each of these 15 groups. Saying this, CMS will thoroughly reassess these fields and determine if there are changes that should be made for CY2020.
CMS Action: No action required for CY2019. CMS will consider this enhancement for CY2020. There is no impact to burden

20.) Plan Benefit Package: Section C OON/POS Pick Lists (14e)

The 14e benefits are grouped together as one benefit in Section C. This often leads to a range being filed for out-of-network with a note explaining which cost shares apply to each 14e service. The benefits in 14e: Other Medicare-covered Preventive Services have been broken out in the Section D plan-level picklists as 14e1, 14e2 and 14e3. United seeks clarification from CMS on whether this split out would be possible for the OON and POS Group pick lists; breaking out 14e in the out-of-network pick lists would allow for a one to one filing, as is done for the in-network cost shares.

Response: This change will be made in the CY2019 Plan Benefit Package software. This will be reflected in the 30-day PRA package.
CMS Action: This change will be made to the PBP software for CY2019. It will have a small reduction on burden (organizations will be able to enter the appropriate cost-sharing in the data entry fields and not in the notes fields).

21.) Plan Benefit Package: Section C PBP Data Reports

United noticed that the "Export to PDF" option was removed from the 2017 PBP software. To obtain a data report in this format, one must now export to Excel, open the Excel file, and then convert to PDF. We believe that these extra steps can add a significant amount of time to the process. United respectfully requests that CMS add the "Export to PDF" functionality back into the PBP software.

Response: As noted above in comment #3, the PDF formatting is not 508 compliant and was required to be removed.
CMS Action: No action is required. There is no impact to burden estimates.

22.) Plan Benefit Package: Section C Skilled Nursing Facility Benefit Period (2, Base 10)

In this section, the question "What is your SNF benefit period?" is disabled when the benefit is filed as $0 per stay or $0 days 1 - X. Further, if a plan files additional days with a cost share, the question is still disabled. United requests CMS enable this question for all scenarios so it allows plans to capture consistent data across all benefit set-ups.

Response: This change will be made in the CY2019 Plan Benefit Package software. This will be reflected in the 30-day PRA package.
CMS Action: This change will be made to the PBP software for CY2019. It will have a small reduction on burden (organizations will not have to clarify benefit periods in the notes fields).

23.) Plan Benefit Package: General Copy Plan
Currently, the copy (plan to plan) function in the PBP software for Group plans will copy over the values. When one plan is copied to many, only one of those plans will show as “Plan Ready for Upload.” We believe that all plans should update to "Plan Ready for Upload" in this scenario and not require an additional “Exit Validate.” United respectfully requests CMS update the PBP software to function for the Group plans, as it does for the Individual plans.

Response: The software is working per design. The PBP requires all plans to review data after a plan copy is performed, which is why the plans are not automatically changed to the status of "Plan Ready for Upload." This is standard for all plans whether the plan is an Employer or non-Employer plan. This is to ensure plans verify their bid submission before uploading this data.
CMS Action: No action is required. There is no impact to burden estimates.

24.) Plan Benefit Package: Standard bid copy. Group plans do not require Sections B and C to be filled out with standard bids. However, there were a few instances in recent years when copying from one Group plan to another (or multiple) would cause Sections B and C to open and be "required" entry points. For that reason, we ask CMS to please ensure that the copy plan (same year) feature in the PBP does not open up Sections B and C for Employer Group Waiver Plans (EGWPs) (800 series) PBPs.

Response: The software is working per design. This happens when an organization attempts to copy data prior to verifying their data in Section A of the PBP software. In CY2018, CMS added an edit rule to notify plans that these sections will not copy. CMS has purposefully done this so plans can be sure to submit meaningful bids, instead of copying data without reviewing.
CMS Action: No action is required. There is no impact to burden estimates.

25.) Plan Benefit Package: General Training Version of the Software
United asks CMS to provide a generic training version of final PBP software for development and internal review purposes by plans. Similar to the beta PBP software that is released, we ask that CMS provide a training version of the final PBP software that does not require a “real” user identification. This would be for local use only with samples of all plan types and use of “virtual” contracts similar to the beta software.

Response: While this comment is outside the purview of this PRA package, a general training of the PBP software is anticipated to be available on cms.gov for CY2019. Additional details will be provided closer to the release of the final software.

CMS Action: A training version of the PBP software will be provided on cms.gov. There is no impact on burden as this comment is outside the purview of this PRA package.

26.) Plan Benefit Package: General Authorization Question Updates

The authorization questions in Section B have been updated from "Enrollee must receive Authorization from one or more of the following:" with five selection options to "Is authorization required?" with "Yes/No" responses. It is now unclear whether plans are still expected to only file requirements that are the responsibility of the member and might impact benefit coverage, or if CMS is asking plans to enter prior authorization (PA) requirements that might be in the provider contract and impact the provider payment, but would not impact a member's benefit coverage. United asks CMS to specify what it would like entered for PAs.

Response: As defined in the MMCM Chapter 4 Section 110.1.1., "prior authorization" is a process through which the physician or other health care provider is required to obtain advance approval from the plan that payment will be made for a service or item furnished to an enrollee. Unless specified otherwise with respect to a particular item or service, the enrollee is not responsible for obtaining (prior) authorization. CMS expects plans to answer "Yes" to the PBP question "Is authorization required?" in accordance with the Chapter 4 definition. Plans may further describe the authorization requirements in the notes if specific detail is necessary.
CMS Action: No action is required. There is no impact to burden estimates.

27.) Medicare & You

When the OON cost share aligns with the INN cost share, the amount is only printed once (ex. $10 instead of $10/$10). However, this may cause confusion for members when looking at an HMOPOS that does not cover all benefits OON because this scenario also only prints one cost share (ex. $10 instead of $10/Not Covered). We recommend that the INN and OON cost shares (or "Not Covered" if a benefit was not filed on a plan) for PPO and POS plans both be printed. Additionally, United requests CMS add an indicator or display for when the Maximum Out-of-Pocket is unlimited.

Response: This comment is outside of the purview of this PRA package. This commenter should direct their comment to the Office of Communication for consideration in the Medicare & You Handbook.
CMS Action: No action is required. There is no impact to burden estimates.

28.) Medicare Plan Finder

Currently, supplemental benefits do not specify that they may be periodicity limited (e.g., Transportation, routine foot care. United requests CMS pull in/import the benefit's filed periodicities from the PBP to the Medicare Plan Finder to provide better data for Medicare eligibles.

Additionally, the filed urgent care coverage is printable, yet if the plan also covers urgent care worldwide only, "always covered" is added to the view versus also including the separate and different cost share for urgent care worldwide (e.g., H0543-138). United asks that CMS pull in/import the filed cost share for worldwide urgent care from the PBP to the Medicare Plan Finder to provide better data for Medicare eligibles.

We have found that the sentence "There may be limits on how much the plan will provide." is not printing for Hearing services, dental services and vision services on this plan (e.g., H0543-138) when it has specific benefit periodicities. However, this sentence is showing up on other plans . We requests that all plans display "There may be limits on how much the plan will provide." next to benefits in Medicare Plan Finder when applicable, or that CMS pull in/import the benefit's filed limits and periodicities from the PBP.

We recommend that CMS use consistent verbiage across all plans in Medicare Plan Finder to mitigate any possible confusion for Medicare eligibles.
Furthermore, MS$0 DSNP does not include "always covered" next to emergency and urgent care cost share. This plan (H0169-001) covers these benefits worldwide as well. For consistency across all plans in Medicare Plan Finder, United asks that CMS display "always covered" next to emergency and urgent care cost shares for MS$0 DSNPs that have worldwide coverage.
When Medicare-covered benefits are filed with a referral requirement and the supplemental benefits are filed without a referral, the supplemental benefits are incorrectly displaying referral required. For example:
- Hearing Exam
- Comp Dental
- Vision Exams and Eyewear
- Foot care/Podiatry

We asks CMS to add additional referral questions to the PBP software that are specific to Medicare covered benefits and supplemental benefits. Breaking the referral question out in this way would allow for a more accurate filing, reduce the number of filed notes, and provide better data for members in Medicare Plan Finder.

Response: The first part of this comment relates to the Medicare Plan Finder display. This is outside of the purview of this PRA package. This commenter should direct their comment to the Office of Communication for consideration. Regarding adding different referral questions for Medicare-covered vs. supplemental benefits in the PBP software, CMS contends this is unbundling of benefits and provides a very confusing benefit design.
CMS Action: No action is required. There is no impact to burden estimates.

29.) Formulary Submission
Following the annual formulary submission for CY 2017, CMS changed the timing for submitting criteria update requests during the calendar year. Criteria update requests were required to be submitted prior to the release of the monthly formulary reference file (FRF). This change in timing does not provide plan sponsors the opportunity for criteria updates during the submission window immediately following the receipt of a monthly FRF. As a result, monthly formulary submissions receive line-level rejects when criteria does not match the monthly FRF. The timing change for criteria update requests causes unnecessary rework, review and resubmission for both the plan sponsors and CMS. For example, following the CY 2017 April monthly FRF, PA criteria change requests related to the April FRF were submitted by the May PA criteria deadline. This was followed a few days later by an HPMS email indicating a review concern for this same criteria related to the formulary submission earlier in the month when those criteria could not be updated.

United recommends that HPMS revert to the timing used in CY 2016 for submitting criteria update requests. Reverting to a date similar to that used during CY 2016 (by 9am PST on the last day prior to the monthly formulary submission window) would allow for criteria updates following the release of a monthly FRF to be submitted during the related formulary submission window. The ability to submit the PA criteria change requests after the FRF is received will provide the opportunity for sponsors to update PA criteria during the submission related to that FRF. This will also avoid the related criteria review concerns that occur because plan sponsors did not have the opportunity to update those criteria during the submission immediately following the monthly FRF release.

Response: CMS appreciates the concern raised by this sponsor regarding the timing of the release of the monthly FRF on the deadline for sponsors to submit their monthly UM criteria change request templates. CMS requires time to review these templates to ensure gate opening requests are appropriate. We recognize this may present operational challenges for some sponsors and will thus review this process for CY 2019.
CMS Action: Review the timing of FRF release with monthly UM change request template submission deadline. There is no impact to burden.

30.) Plan Benefit Package (PBP) Rx Section: "Alternative – Enhanced Alternative Characteristics" Data Entry Screen. For CY 2018, the note on the "Alternative - Enhanced Alternative Characteristics" PBP screen that references the Generic and Brand Gap discount was updated to reflect the following instruction:

"The beneficiary cost-sharing for the Defined Standard (DS) gap coverage benefit in CY 2018 is 44% for generic drugs and 35% for brand drugs. The coverage gap discount applies to applicable drugs for all benefit types and must be reflected in each plan's bid.
Thus, the gap coverage section of the PBP is only intended for those enhanced alternative (EA) plans offering additional cost-sharing reductions in the coverage gap through a supplemental Part D benefit. All other benefit types will NOT enter gap coverage information in the PBP. Additional reductions in gap cost-sharing offered by EA plans represents cost-sharing that is significantly better than the defined standard cost-sharing benefits for generic and/or brand drugs that must be offered by all plans. When offering additional cost-sharing reductions for applicable drugs in the gap, the plan liability is first applied to the plan-negotiated price followed by the manufacturer coverage gap discount for applicable beneficiaries.
Please note, the additional gap cost-sharing entered in the PBP is meant to reflect the cost-sharing experienced by the beneficiary at the point of sale. The maximum additional gap beneficiary cost-sharing for generic drugs in CY 2018 is 24%. The CY 2018 maximum additional gap cost-sharing for applicable drugs is 55%, which is inclusive of the 50% manufacturer discount. Therefore the maximum beneficiary cost-sharing that should be entered into the PBP as 27.5%. The PBP cannot accept fractions of a percent therefore the PBP entry must be rounded to reflect a whole percentage."

As noted previously in our feedback on the CY 2018 bid submission process, we identified several operational challenges with the updated instruction, which are highlighted below along with related recommendations for further refining and improving this section of the PBP tool for CY 2019 and future years.

- Brand/Generic Tier Structure. Although the instructions specify that "the additional cost-sharing entered into the PBP is meant to reflect the cost-sharing experienced by the beneficiary at the point of sale" and indicate that the maximum additional gap beneficiary cost-sharing for generic drugs and "applicable" drugs differ, the PBP software does not accommodate reporting of two separate cost-sharing amounts under circumstances where a formulary may include a brand/generic "mixed tier." We recommend that CMS revise the PBP software functionality to reflect the updated instruction and to ensure accuracy.
- Applicable Drug. The updated instruction for this section of the PBP refers to both "brand" and "applicable" drugs. For clarity and to ensure consistent reporting, we recommend that CMS clarify how the agency defines an applicable drug versus a brand drug for purposes of reporting in this section of the PBP.

Response: CMS appreciates this comment and we are aware of the operational challenges that this modification caused to plan sponsors. As a result, for CY 2019, the data for this field will again be entered as it was in CY 2017 and prior years. We will be modifying the instructions on this PBP page to further clarify.
CMS Action: This change will be made to the PBP software for CY2019. It will have a reduction on burden (organizations will not have to clarify benefit periods in the notes fields).

31.) CY 2019 Formulary Submission

2019 Tier Model Options. CMS is proposing three additional Part D formulary tier model options for CY 2019. Specifically, the agency is proposing two new four-tier structures and one new five-tier structure. Currently, Part D sponsors may choose to designate one formulary tier as their Specialty Tier, on which Part D drugs with sponsor-negotiated prices that exceed the dollar per month threshold established annually by CMS may be placed. However, in an effort to address the increased market entry of new high-cost drugs, as well as maintain an affordable and accessible Part D program for beneficiaries, HCSC continues to believe that CMS should permit sponsors to designate two separate specialty tiers, a preferred specialty tier with lower cost sharing and a non-preferred specialty tier.

This approach could provide sponsors with greater leverage in negotiations with manufacturers for certain high-cost drugs, as well as encourage and increase competition among existing specialty drugs. In addition, as more biosimilar products are approved by the Food and Drug Administration (FDA), this two-specialty tier structure could encourage Part D enrollees to substitute lower-cost biosimilar products for the corresponding reference product. This could result in more affordable care for Part D enrollees and lower costs for the Part D program more broadly. In their June 2016 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended that CMS revise their Part D guidance to allow for two specialty tiers, and indicated that if used appropriately, this tier structure could reduce the need for non-formulary exceptions as less cost-effective options could be placed on the non-preferred tier rather than excluded from the plan's formulary. As a result, HCSC continues to strongly recommend that CMS revise the CY 2019 Tier model options to include an additional 6-tier structure that would allow for a preferred and non-preferred specialty tier as described above. We note that in conjunction with this recommendation, we also recommend that CMS revise the tiering exception guidance to permit plan members to obtain a 6th tier non-preferred drug at the 5th tier preferred drug cost sharing level when the 6th tier drug is medically necessary.

Response: CMS appreciates this comment, but this comment is beyond the scope of this PRA submission. The tier model additions in this package were included only to add the remaining possible models that were not included for CY 2018. CMS will consider your comment in future policy.
CMS Action: No action is required. There is no impact to burden estimates.

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

Thank you.