



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: February 5, 2018

SUBJECT: Response to CMS-R-262 30-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 four (4) comments from one organization. CMS has determined there will be no change to the burden estimate that was previously estimated for the package. These comments relate to clarifications as well as the opportunity to provide comments to CMS regarding future policy and regulatory changes. Responses to the comments are below.

Plan Benefit Package (PBP) and Formulary Comments

- 1.) **VBID/MA Uniformity Flexibility.** CMS is proposing to revise Section B-19 of the PBP, "Value Based Insurance Design Model Test," by renaming the section "VBID/MA Uniformity Flexibility" to permit organizations to include in the PBP, MA Uniformity Flexibility (UF) along with the already existing VBID benefit. It appears that this revision is intended to support the proposal in CMS' CY 2019 MA and Part D proposed rule, for the agency to adopt a new interpretation of the MA uniformity requirements outlined in the statute and the corresponding MA regulations, to permit plans to reduce enrollee cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, "provided that similarly situated enrollees (that is all enrollees who meet the identified criteria) are treated the same. For clarity, we recommend that CMS confirm whether our understanding of the intent underlying the proposed change to this section of the PBP is accurate.

Response: CMS can confirm this user's understanding is correct. CMS notes that the uniformity flexibility benefit is not in the proposed rule, but rather CMS is clarifying existing statutory and regulatory authority.

CMS Action: No action required as this is a confirmation of the intent of the Uniformity Flexibility benefit being incorporated into the PBP software.

- 2.) Final upload requirements and layout. If CMS moves forward with the proposed Part D opioid strategy upload as part of the CY 2019 formulary submission process, we strongly recommend that the agency release the final version of the “Opioid Strategy Layout” as quickly as possible and well in advance of the upload deadline to ensure sponsors are afforded sufficient time to prepare submissions that are responsive to the full range of topics and questions on which CMS is seeking feedback.

Response: There is not a specific format or structure to the Microsoft Word® document that will be uploaded into HPMS.

CMS Action: No action is required. There is no impact to burden estimates.

- 3.) Commercial efforts to combat the opioid crisis. As part of the “Opioid Strategy Upload,” CMS is proposing to require Part D sponsors to describe “any programs, initiatives, or other efforts” organizations have in place for commercial lines of business, whether these efforts have been successful, and if there are policy barriers that prevent implementation of these initiatives in Part D. Our understanding is that CMS is not requesting that sponsors submit a full summary of the comprehensive strategy to combat the opioid crisis in commercial plans offered by the same entity, but rather is specifically interested in more streamlined reporting of initiatives employed to combat the opioid crisis that have been successful in commercial plans, but cannot be replicated under the Part D program due to current policy and operational limitations. To support consistency in submissions, we recommend that CMS confirm whether our understanding is accurate, and revise the relevant section of the “Opioid Strategy Upload” as applicable to ensure clarity.

Response: Although sponsors are welcome to submit a full summary of their commercial strategy to combat the opioid crisis, we welcome any successful private sector initiatives or programs that could be implemented in Part D. In addition, CMS would like sponsors to identify any policy barriers that impede the implementation of successful commercial initiatives or programs in Part D.

CMS Action: No action is required. There is no impact to burden estimates.

- 4.) Future Part D policy development. As noted above, CMS intends to utilize information received from the proposed opioid strategy uploads to help inform potential future policy changes and/or development of new policy related to combatting the opioid crisis under the Part D program. We believe it will be important for Part D plan sponsors to have an opportunity to review and comment on any proposed policy changes before they are finalized, as these steps will allow plans to provide CMS with feedback informed by practical experience and will permit the agency to consider potential operational challenges before processes and guidance become final. As a result, we recommend that CMS provide a meaningful opportunity for comment on any future program changes related to combatting the opioid crisis under Part D, before any such changes are finalized.

Response: We appreciate your concerns and would follow appropriate notice and comment processes should new requirements or expectations be implemented.

CMS Action: No action is required as this comment relates to future regulatory/policy changes. 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.