Responses to Comments Received on the Revised CMS-10788
Federal Register 60-Day Notice (89 FR 6118)

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A. Introduction

We received four comments on specific issues regarding the notice of the revised Prescription Drug Data Collection (RxDC) PRA package published in the Federal Register on January 31, 2024 (89 FR 6118). The 60-day comment period closed on April 1, 2024.

The PRA package contains the RxDC Reporting Forms that issuers must file with CMS each year by June 1 and the accompanying Reporting Instructions. The PRA package modifies the RxDC Reporting Instructions that were previously approved by OMB under OMB Control Number 0938-1407.

The comments addressed clarification of the instructions and conveyed concerns about data quality, reporting burden, and the submission deadline. The summary below sets forth each comment and our response.

B. Comments on the 2023 Prescription Drug Data Collection (RxDC) Reporting Instructions and Templates

1. All four comments requested that the Departments obtain OMB approval and publish finalized changes to the reporting instructions at least six to 12 months in advance of the reporting deadline. Commenters expressed concern about the ability of the reporting entities to accurately implement the changes, given that this data collection involves data sharing and coordination among multiple entities. One comment suggested that in the alternative, the Departments should grant good faith reporting relief and/or defer enforcement of the June 1, 2024 deadline. Two comments additionally recommended that the Departments begin holding webinars with stakeholders five to seven days after publishing the proposed changes to the instructions.

   Response
   The Departments appreciate concerns expressed by the commenters and acknowledge the challenges faced by the reporting entities and the potential impact of the current timeline on the quality of the reported data. The Departments will continue to strive to finalize changes to the instructions significantly in advance of the reporting deadline. As the program matures, the Departments also anticipate that the need for clarifications and for substantive changes will diminish. In addition, the Departments agree with the recommendation to host

webinars shortly after release of the proposed changes to the instructions, and will seek to do so, subject to resource availability.

2. Three comments requested that the Departments continue to suspend enforcement of the aggregation restriction for another year (until June 2025), as it requires extensive coordination across multiple reporting entities and their clients within a constrained timeframe. Two comments similarly requested that the Departments defer enforcement of the requirement to report pharmacy benefits enrollment on the D6 template for a year, expressing concerns with the ability to implement this timely, and seeking clarification regarding enrollment methodology.

   Response
   The Departments note that the aggregation restriction is a requirement in the regulations as well as the initial reporting instructions, and its suspension was specific to the initial reporting years. In addition, given the difficulties encountered by the Departments in analyzing plans' and issuers' data spread across multiple reporting entities, both consistent aggregation (that will be achieved under the aggregation restriction) and the addition of Rx enrollment to D6 are critical to the Departments' ability and efforts to continue to allow multiple reporting entities to submit the data of plans and issuers. However, the Departments recognize that implementation will present stakeholders with logistical challenges that may result in reporting entities being able to submit only partially accurate, complete, or consistent data with respect to these two requirements by the June 1, 2024 deadline. The Departments' approach in implementation of this requirement will focus on assisting those reporting entities who are working diligently and in good faith to comply with this requirement when reporting data in 2024 and toward achieving full compliance. The Departments also clarified in the instructions that member months on D6 should be calculated as described in the definition for life-years.

3. Three comments related that issuers continue to experience difficulty obtaining complete and accurate employer vs. member premium and other information from group health plans. Two comments requested that the instructions clarify that employer group health plans that fail to provide this information to their reporting entities must submit the data directly to the Departments. One comment recommended an enforcement safe harbor for reporting entities that are unable to obtain the necessary information from plan sponsors despite a good faith effort, while another comment supported the exclusion of plans that did not provide the necessary information from calculation of average monthly premium in section 6.1 of the proposed instructions. One comment noted that the simplified approach of dividing the total annual premium by 12 could lead to misleading numbers in circumstances involving partial-year data.

   Response
   The Departments recognize the difficulty faced by issuers in complying with statutory requirements to report data which may not be in their immediate possession and which they may not be able to access despite appropriate contractual arrangements and good faith efforts. The Departments note that section 6.1 directs issuers to exclude plans that did not provide the necessary information from the calculation of average monthly premium in the issuer's D1. The Departments further note that section 3.8 of the proposed instructions

already stated that if an issuer or vendor does not submit P2 and D1 (or other required files) on a plan's behalf, then the plan must submit P2 and D1 directly to CMS. However, the Departments added the same clarification to the description of average monthly premium in section 6.1 of the instructions. The Departments also confirm that division of total premium by 12 in section 6.1 is deliberate as it will enable the Departments to obtain accurate and consistent annualized data in all circumstances.

4. Two comments recommended making the Form 5500 Plan Number optional because it is not received or stored by third-party administrator reporting entities and issuers.

   Response
   The Departments revised the instructions to clarify that reporting entities that do not obtain this information from the plan may leave this field blank.

5. Three comments requested clarification regarding the carve-out description field in D2. Two comments questioned whether "Medical only" is an appropriate carve-out category. One comment recommended removing references to "the majority of the plan's other benefits" to relieve reporting entities from the need to analyze services provided to a plan by other service providers.

   Response
   The proposed instructions added details to the description of carved-out benefits in response to questions about how to report such benefits and how to identify the relevant coverage arrangements, as well as to improve the Department's ability to differentiate between subsets of data submitted by multiple reporting entities. The Departments revised the instructions to clarify that the reporting entity does not need to analyze services provided to a plan by other service providers, and that "Medical only" is used to indicate that a different reporting entity will submit data regarding the plan's pharmacy benefit.

6. Two comments recommended enabling reporting entities to use actual dates for prior plan year beginning and end dates for termed plans in P2, instead of the workaround dates that were designated in the proposed instructions to prevent the system from rejecting submissions containing plan year end dates in the year prior to the reference year. One of these comments additionally suggested using an indicator or null values as an alternative, and expressed concern about the burden of the additional required reporting.

   Response
   The proposed instructions added clarification regarding prior plan year beginning and end dates for termed plans in response to questions about the data collection system's limitations in being able to accept such dates. The Departments revised instructions to clarify that inclusion of such plans in P2 remains optional and that null values can be used in lieu of the workaround 01/01/2023 and 01/02/2023 dates.

7. One comment requested clarification regarding whether inclusion of non-drug items such as medical devices that are not used in tandem with drugs is appropriate in the medical benefit drugs category on D2.

Response

No changes were made to the instructions based on this comment. The Departments note that the referenced provision in section 8.1 of the proposed instructions refers to pharmaceutical supplies, medical devices, nutritional supplements, and OTCs *in the appropriate spending category* in D2 if the products are covered under a plan's medical benefit (*emphasis added*). Therefore, medical devices unrelated to medical benefit drugs should not be reported in the medical benefit drug category on D2. The clarification in the proposed instructions was intended to clarify that all such items that are covered under the medical benefit should be reported in the relevant category on D2 (hospital, primary care, specialty care, or other), while some items may also need to be reported in the medical benefit drugs category as appropriate. The Departments welcome suggestions for how to further improve the clarity.

8. One comment inquired whether the Departments intend to update the CMS crosswalk and data validations technical documents annually or only as needed.

   Response

   The Departments anticipate that the CMS crosswalk is likely to require annual updates, for example, to include new drugs. The Departments expect to update data validations only as needed, for example, to reflect new or modified data elements, or if new validations are determined to be necessary for any required data elements that experience poor compliance with the instructions.