Appendix 1 - Responses to Comments Received on the Emergency CMS-10788 Federal Register 60-Day Notice (86 FR 66662)

Table of Contents

A. Introduction

On November 23, 2021, the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (Treasury) (collectively, the Departments) published the Health Prescription Drug and Health Care Spending Interim Final Rule (IFR) (86 FR 66662). Concurrently, the Centers for Medicare & Medicaid Services (CMS) posted the Paperwork Reduction Act (PRA) package in the Federal Register (CMS-10788). Thirty-five unique comments were received. In addition, CMS received ten requests for clarification after the public comment period closed.

The PRA package contains reporting instructions and the file layouts for the required plan lists and data files (the "RxDC report"). There are three plan list files to identify plans in the submission, separated by individual and student markets, group health plans, and FEHB carriers. There are eight data files to collect prescription drug and health care spending data, aggregated by market segment and state. Group health plans, issuers, and FEHB carriers (or their contracted reporting entities) must submit the annual RxDC report to CMS no later than one year after the date the CAA was enacted, and not later than June 1 of each year thereafter. Due to the significant operational challenges that regulated entities may face in meeting the initial deadlines for the section 204 data submissions, no enforcement action will be taken against a plan, issuer, or carrier that does not report the required information by the first statutory deadline for reporting on December 27, 2021 or the second statutory deadline for reporting on June 1, 2022, and that instead submits the section 204 data submissions for the 2020 and 2021 reference years by December 27, 2022.[1]

The PRA package modifies the reporting instructions (2020 Prescription Drug Data Collection (RxDC) Reporting Instructions) and file layout previously approved under OMB control number 0938-1407.

Most comments addressed clarification of the instructions, treatment of aggregation, cost-sharing payments, and the definition of a prescription drug. The summary below sets forth each category

[1] See FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Part 49, Q12, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf and https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

of comments and our response.

B. Comments on the 2020 Prescription Drug Data Collection (RxDC) Reporting Instructions: Prescription Drug and Health Care Spending

1. We received a request to explain the difference between the plan lists and data files.

   Response
   We provided additional details in the instructions to describe the difference between the plan list and data files.

2. We received three inquiries about RxDC drug and therapeutic classes and the relationship between an NDC and a RxDC drug name.

   Response
   We updated the instructions to provide additional detail about RxDC drugs and therapeutic classes. We updated the example to clarify the relationship between an NDC and an RxDC drug code. We clarified how to sort prescription drug data to determine the top 50 most frequently dispensed brand name drugs, the top 50 most costly drugs, the top 50 drugs with the greatest increase in spending, and the top 25 drugs with the highest amount of rebates.

3. Two commenters raised concerns over the collection of beginning and ending plan dates being out of sync with the calendar year aggregation for spending data.

   Response
   We updated the instructions to clarify how to report information for non-calendar year plans. Specifically, plans and issuers must report the non-calendar year plan beginning and end dates and use two rows in the plan list for plans that renew mid-year. In the data files, they must only include the portion of experience attributable to the reference year, rather than the entirety of each plan year.

4. We received one request to be more inclusive with the definition of bona fide service fees, such as detailed disclosure of service fees that are tied to a therapeutic class or a specific drug, if a contract with a regulated entity creates such a linkage. Another commenter suggested defining bona fide service fees as fees that meet the Bona Fide Service Fee (BFSF) Test used in the Medicare program to determine if a fee should be treated as a fee versus a price concession or some other form of revenue. One commenter suggested disaggregating bona fide service fees from the broader definition of remuneration in future years.

   Response
   We made no changes based on this comment. As noted in the IFR, BFSFs are not always intended to directly affect the cost or utilization of specific prescription drugs. Therefore, the agencies do not require these fees to be reported separately by therapeutic class or drug. We note that the definition of BFSFs in the RxDC instructions is the same as the four-part test used by the Medicare Part D program. We used the four-part test to reduce the compliance

burden for issuers and PBMs that have already built reporting capabilities for the Medicare program.

5. Three commenters suggested revisions to the definition of total spending. One suggested revising the total spending definition, as it appeared to be an error that manufacturer cost-sharing assistance should be subtracted from total cost sharing. Another commenter requested clarifying the total spending definition regarding subtracting any federal or state reinsurance payments, since reinsurance would not be attributable to specific drugs.

   Response
   We updated the instructions to specify that manufacturer cost-sharing assistance must be subtracted from total spending, to the extent the information is known and has an impact on total spending. We made no changes to the definition of cost-sharing. As noted in the IFR, we are collecting data on manufacturer cost-sharing assistance separately and will incorporate such reductions into the analysis conducted for the section 204 public report.

   We also updated the instructions to specify that reporting entities should use a reasonable method to account for the subtraction of federal or state reinsurance payments when reporting total spending at the drug or therapeutic class level.

6. One commenter suggested requiring more granularity to cost-sharing by therapeutic class. Another suggested that reporting entities quantify the impact of manufacturer rebates separately according to impact on cost-sharing versus the impact on premium. Another commenter indicated that we should not collect information on manufacturer cost-sharing assistance, asserting that issuers and PBMs do not have the capability to track most manufacturer cost-sharing assistance or "coupons".

   Response
   We made no changes based on these comments. We note that the reporting instructions require plans, issuers, and carriers to provide a qualitative assessment and a quantitative estimate of the impact of rebates, fees, and other remuneration on premium and cost-sharing, to the best of their abilities. We may update the requirements related to quantitative reporting in the future.

7. One commenter suggested capturing more details about spending on drugs covered under a hospital or medical benefit because drugs administered under these benefits are significant cost drivers in the health care industry. Another commenter suggested capturing National Drug Codes (NDC) for medical specialty drugs, since they are billed through a doctor's office or hospital and paid through the medical benefit.

   Response
   We made no changes based on these comments. As noted in the IFR, we recognize that prescription drugs covered under a medical benefit constitute a significant portion of prescription drug spending and include some of the costlier drugs. However, in recognition of the difficulty of isolating the cost of the prescription drugs included in bundled payments or other alternative payment arrangements, we only require reporting on total spending and

not detailed information by drug or therapeutic class. The agencies may modify the reporting requirements regarding the drugs covered under the hospital or medical benefit in the future.

8. Three commenters opined on the difficulty in obtaining the premium amounts paid by the employer versus the amount paid by the employee. One commenter suggested excluding premium and life-years for groups for which the portion paid by the employer is not available. Another commenter recommended only requiring reporting of total premiums, rather than premiums paid by employer versus premiums paid by employee.

   Response
   We note that it is a statutory requirement for plans and issuers to report average monthly premium paid by employers and average monthly premium paid by enrollees. However, we recognize that issuers may not be able to obtain the required information from former clients or from employers that have gone out of business. Therefore, for the 2020 and 2021 reference years only, we revised the instructions to accept estimated values when, despite a good faith effort, an issuer has been unable to obtain the information from a former client.

9. One commenter suggested reconciling the definition of earned premium with existing fillings, such as Supplemental Health Care Exhibit or the 12/31 column of the MLR Annual Reporting Form.

   Response
   We made no changes based on this comment. The RxDC definition of earned premium is the same is the same as the definition for the 3/31 column of the MLR Annual Reporting Form. The 3/31 column accounts for earned premium payments for policies in effect during the reference year that are processed and paid in the three months following the end of the reference year.

10. Seven commenters suggested that we provide more details on the definitions of the spending categories, such as by using a breakdown of claims categories, since the healthcare industry lacks uniformity in defining terms such as “wellness” or “hospital” spending. Several commenters suggested providing a uniform approach to defining provider types (primary care versus specialty care). Commenters suggested that a list of taxonomy codes and services by CPT/HCPCS could be one method of ensuring uniformity.

    Response
    We added more details to the reporting instructions about how spending should be broken down by claims types and place of care. We also provided taxonomy codes and procedural codes (CPT/HCPCS).

C. Comments on the RxDC Data Collection System

1. We received eight comments on the data collection system. Many commenters expressed support for a data collection system that allows multiple entities to report different subsets of the required information for a plan, issuer, or carrier.

Response

We made no changes based on these comments. We are collecting data using the Health Insurance Oversight System (HIOS). HIOS will accommodate submissions by multiple reporting entities.