



April 1, 2024

Filed electronically via federal eRulemaking Portal: www.regulations.gov.

Ms. Chiquita Brooks-LaSure
CMS Administrator
U.S. Department of Health and Human Services
U.S. Centers for Medicare & Medicaid Services
750 Security Boulevard
Baltimore, MD 21244

Mr. William N. Parham, III
Director, Paperwork Reduction Staff,
Office of Strategic Operations & Regulatory Affairs
U.S. Centers for Medicare & Medicaid Services
750 Security Boulevard
Baltimore, MD 21244

RE: 2023 Prescription Drug Data Collection (RxDC) Reporting Instructions (CMS-10788)

Dear Administrator Brooks-LaSure and Director Parham:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to provide public comments on the U.S. Centers for Medicare & Medicaid Services' (CMS) revisions to its prescription drug pricing and spending transparency program as required by section 204 of Title II (Transparency) of Division BB of the Consolidated Appropriations Act of 2021. On January 31, 2024, CMS published a Paperwork Reduction Act¹ opportunity for submitting public comments on burdens related to the data submission processes and data fields for the 2023 Prescription Drug Data Collection (RxDC). The 2023 RxDC Reporting Instructions (Reporting Instructions) and Supporting Statement were issued on the same date.² CMS oversees the data collection on behalf of the U.S. Departments of Health and Human Services, Treasury, Labor, and the Office of Personnel Management (OPM) ("the Departments").

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and through the exchanges established by the Affordable Care Act. Our members' clients include group health plans and health insurance issuers, including the carriers who offer coverage under the FEHBP overseen by OPM. We restrict our comments to issues germane to PBMs, knowing that issuers and group health plans have different needs and interests in these data and this program.

1. CMS Needs to Release Clarifications Earlier

The current schedule for releasing updates and clarifications to the Reporting Instructions does not allow for sufficient lead time for organizations to prepare and submit their reports. Releasing

¹ 89 Fed. Reg. 6118, January 31, 2024.

² CMS. "Prescription Drug Data Collection (RxDC) Reporting Instructions. Last updated January 2024. Available at https://regtap.cms.gov/reg_librarye.php?i=3860, last accessed March 19, 2024.



the Reporting Instructions at the end of January leaves only four months for data owners to compile data files and then provide these to issuers, plans, third-party administrators (TPAs) or other vendors, and then for these entities receiving data files, in turn, to incorporate the data into their filings or pass them down further to the final reporting entities responsible for collating, merging, reviewing, and performing final quality assurance activities to ensure that the submissions are complete and accurate.

Since data may need to be shared multiple ways across multiple vendors, the short window simply does not allow adequate time to vet requirements, design, code, test and implement changes. For example, the Reporting Instructions added a new column to D6 to collect enrollment information, which will require further data sharing and coordination with plan sponsors.

We recommend that a minimum of nine months be provided between the issuance of the Reporting Instructions and the deadline for submission of the files. We also ask that CMS convene a REGTAP call within five-to-seven business days after changes are released to review details and discuss specific scenarios and subsequent impact. We request that one be held as soon as possible for the 2023 reporting year.

PCMA recommendation: CMS should release the Reporting Instructions at least nine months before the submission deadline and convene a REGTAP call to discuss the details of any changes.

2. Reporting Prior Plan Years

The Reporting Instructions added instructions clarifying how to represent plans in data field P2, when the plan contributes to the prior year and restated fields but not to the current year's fields, and states that if a plan is included on the plan list solely because it contributed to prior year's columns (D5) or the restated rebate column (D6, D7, D8) but didn't contribute to fields for the current reference year, the report must show 01/01/2023 and 01/02/2023 as the plan year's beginning and end dates, respectively.

We are concerned that this "default" means of identifying prior plan years by using dates could conflict with data integrity best practices. In effect, reporting entities are being asked to report fictitious and inaccurate dates that may conflict with actual dates. It would be possible for some plans to have been active for this specific two-day period in 2023, and for them, this reporting would cause confusion. In addition, the instructions imply that this change should be "hard coded," yet may change again in subsequent years. For example, for reference year 2024 reports which are due 6/1/2025, there is an implication that these plan dates would be 1/1/2024 and 1/2/2024 respectively. Alternatives to consider are:

- Establishing a "Prior year costs/restated rebates only" indicator column to be added to P2.
- Consider using the actual prior year dates or designate NULL values for the dates for this scenario. Used in conjunction with the Reference Year, the P2 report should provide a means for CMS to achieve their objective.



PCMA recommendation: CMS should reconsider use of actual dates for the prior plan year, since this requires reporting entities to submit incorrect data that could conflict with actual plan dates.

3. Announced Enforcement of Aggregation Restriction (Section 5.6)

The Reporting Instructions states that, starting with the RxDC report for the 2023 reference year, the aggregation restriction will no longer be suspended. This aggregation restriction requires that data submitted in files D1 and D3 – D8 not be aggregated at a less granular level than the aggregation level used by the reporting entity that submitted the data in file D2 Spending by Category.

We are concerned that the level of coordination to meet this aggregation requirement among PBMs, TPAs and other reporting entities cannot be achieved by the filing deadline of June 1, 2024 for the 2023 reporting year. Reporting Entities responsible for D1 and D3-D8 report submission do not have visibility into all reporting entities filing D2 on behalf of mutual plans. Specifically, self-funded plans' vendors have their own contractual obligations to plan sponsors that do not include any direct interaction with their direct medical carrier. The PBM would essentially need to know how the medical TPA is aggregating because D3-D8 aggregation must align with the aggregation on D2. This is not feasible logistically, especially given the time frame.

PCMA recommendation: CMS should not enforce the aggregation restriction for the 2023 reporting year. Much greater lead time and coordination would be needed for reporting entities to comply with this aggregation requirement.

4. Added Column to D6 to collect enrollment (Section 8.3)

The Reporting Instructions require the reporting of the total number of member months covered during the reference year under the pharmacy benefit for which a reporting entity is reporting pharmacy spending. This is a major new reporting element in that it looks for information solely related to the pharmacy benefit. As such, it will be very challenging to accomplish before the June 1, 2024 submission deadline. It is also not clear how the number of members within a given month must be determined, and whether, for example, reporting entities will need to explain the member inclusion methodology used, such as what day of the month was used. We recommend instead that CMS defer enforcement for Reporting Year 2023 reporting of the new enrollment column otherwise due June 1, 2024. Given the magnitude of the change and the clarifications needed, we ask that CMS exercise enforcement discretion with respect to this new requirement.

PCMA recommendation: Given the magnitude of this new requirement and the clarifications required, we ask that CMS exercise enforcement discretion for this requirement for the 2023 reporting year.



We appreciate the opportunity to submit comments based on the updated guidance for the 2023 Reporting Year. We appreciate CMS's efforts in addressing stakeholder's concerns and encourage CMS to continue to engage stakeholders throughout the data submission process. If you need additional information, please contact me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Senior Vice President, Policy & Regulatory Insights

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA