BlueCross BlueShield Association

750 9th Street, NW
Washington, D.C. 20001
www.BCBS.com

April 1, 2024

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Marty Walsh
Secretary of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

Director Kiran Ahuja
Office of Personnel Management
1900 E Street, NW
Washington, D.C. 20415

RE: Information Collection Request (ICR) and Paperwork Reduction Act (PRA) Materials Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (89 FR 6118, CMS-10788)

Dear Secretary Becerra, Secretary Yellen, Secretary Walsh, and Director Ahuja:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on the information collection request regarding the Prescription Drug Data Collection (RxDC) included in Section 204 of Title II of Division BB of the Consolidated Appropriations Act (CAA), 2021, as issued in the Federal Register on January 31, 2024 (89 Fed. Reg. 6118).

BCBSA is a national federation of independent, community-based and locally operated BCBS companies (Plans) that collectively cover, serve, and support 1 in 3 Americans in every ZIP code across all 50 states and Puerto Rico. BCBS Plans contract with 96% of hospitals and 95% of doctors across the country and serve those who are covered through Medicare, Medicaid, an employer, or purchase coverage on their own.

We appreciate the opportunity to provide comments and recommendations as the Departments of Health and Human Services, Labor, and Treasury (the Departments) and the Office of Personnel Management (OPM) further refine the reporting standards. BCBSA supports a reporting system that is administratively efficient, protects proprietary and confidential information, and reduces burden on the Departments, OPM and reporting entities.

BCBS Plans and other reporting entities have complied with the initial RxDC requirements under the CAA. We understand changes to the reporting instructions and templates are needed in first reporting cycles, but proposed changes close to the reporting deadline can create administrative burdens on reporting entities and businesses sharing data for this filing. In order to mitigate the impact of late changes to RxDC reporting instructions, **BCBSA's overarching recommendation is that future RxDC updates via ICR and PRA be finalized by the fourth quarter of the year preceding a reporting**

deadline in order to allow reporting entities adequate time to incorporate any changes into their reporting processes and procedures and, if necessary, contract terms. BCBSA also recommends the following:

- **[Section 4.2] Remove the Form 5500 Number Field:** We recommend the Departments not require inclusion of the Form 5500 number field located on page 14 of the RxDC reporting instructions. While TPAs and issuers may assist employers by providing information for the Form 5500, the Form 5500 Plan Number is not a value received or stored by TPAs and issuers. We support flexibility to use a unique group health plan number, such as capturing the federal employer identification number (FEIN), without a requirement to include Form 5500 numbers.
- **[Section 4.2] Additional Clarity Surrounding the Carve Out Description "Medical Only" Category**: BCBSA also seeks additional clarity surrounding the "Medical Only" value for the carve-out description in the P2 Group Health Plan List on page 15 of the reporting instructions. The carve-out description field is required when a reporting entity is submitting data for a carved-out benefit and a different reporting entity will report on the majority of the plan's other benefits. "Medical only" is listed as a category for a carved out benefit, however that category would apply to the bulk of a plan's benefits even if drugs and/or behavioral health benefits are carved out. BCBSA would like some clarity surrounding the inclusion of the "Medical only" category in the carve-out description given its lack of specificity and whether it is meant to signify "physician only."
- **[Section 5.6] Non-Enforcement of Aggregation Restrictions for an Additional Year:** BCBSA recommends CMS delay the aggregation restrictions until the 2024 reference year reporting (due June 2025). We support another year of nonenforcement of the aggregation restrictions to grant CMS time to establish a system for aligning the level of aggregation for reporting entities. This includes clarifying which reporting entity (or plan sponsor) is responsible for establishing the aggregation level for other reporting entities. For example, does the plan sponsor or the reporting entity filing the D2 file establish the aggregation level for all other reporting entities (e.g., pharmacy benefit managers)? Given the short window until the June 1, 2024, reporting deadline, BCBSA believes moving forward with the aggregation restrictions would create inconsistencies across data fields, cause additional confusion and may result in inaccuracies in reporting files.
- **[Section 6.1] Preserve the ability to exclude group health plans in columns E & F that do not provide employer-paid and member-paid premium amounts to reporting entities; direct plans to report data directly to CMS**. BCBSA supports the proposed approach in the reporting instructions to exclude group health plans that have not provided necessary premium information. Reporting entities currently request premium amounts from employers, however there will always be data gaps from employers who do not respond due to a lack of resources (e.g. no dedicated HR/benefit staffer), employers switching to a different insurer, or business terminations.

  BCBSA recommends CMS state in the reporting instructions that group health plans failing to report premium data to reporting entities would need to submit that data directly to CMS. BCBSA would not support a change in the proposed reporting instructions for 2023 for entities to collect missing premium data from group health plans that would necessitate more

stringent outreach to plans and manual data entry of plan responses. These requirements would be cost and time prohibitive.

- **[Section 8.1] Additional Clarity Surrounding the Inclusion of Non-Drug Items to the Medical Benefit Drug File**: BCBSA does not support the addition of non-drug items, including devices, in the medical benefit drug file. Section 8.1 stipulates the inclusion of, "information for 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." While some medical devices, such as an insulin pump, may be used with drugs, other devices are not used at all in tandem with a drug. BCBSA believes the current language in this section is too broad and requests additional clarity.

We appreciate your consideration of our comments. If you have any questions or want additional information, please contact Paul Eiting at paul.eiting@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Policy Analysis
Office of Policy & Advocacy

F 202.331.7487
ahip.org

April 1, 2024

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer

RE: Prescription Drug and Health Care Spending (CMS-10788; OMB: 0938-1407) —AHIP Comments

Dear Sir or Madam:

Thank you for the opportunity to provide comments on the Paperwork Reduction Act (PRA) notice for the collection of Prescription Drug and Health Care Spending data (RxDC) by the Office of Personnel Management (OPM), as well as the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (collectively, "the Departments.")

AHIP[1] shares the goal of lowering health coverage premiums through lower spending on prescription drugs, which necessitates identification of which drugs are the primary drivers of increased costs for patients and plans. AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.

Prescription drugs play an important role in our health care system by treating or preventing disease and helping patients heal and function. For far too long, pharmaceutical manufacturers have continued to push through significant and unreasonable price increases for their life-saving products while setting unsustainably high prices for newly approved and new-to-market drugs. These initial high prices and subsequent increases place severe burdens on patients that drive up costs for employers, consumers and, ultimately, the Federal government through higher premiums and out-of-pocket costs.

AHIP appreciates the Departments' substantive engagement of stakeholders and responsiveness to our feedback and comments throughout the implementation process. The technical assistance webinars that preceded the December 27, 2022 and June 1, 2023 reporting deadlines were particularly helpful as a resource for our members, and we recognize the time and effort staff put into them. In detailed comments below, we elaborate on issues related to the newly proposed reporting requirements and pose technical questions for consideration on the proposed update to the reporting instructions (last updated January 2024).

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

Good Faith Reporting Relief
AHIP and our members appreciate the good faith reporting relief that was granted for the December 27, 2022 reporting. Following the release of several late changes and answers to frequently asked questions, the relief allowed insurers to report their data to the best of their ability. We recognize the efforts of Department staff in providing robust technical assistance and support throughout the process. However, the current proposed reporting instructions were released only four months before the June 1, 2024 reporting deadline, and our members are extremely concerned about their ability to comply fully with the proposed instructions, including some entirely new reporting variables and calculation methodologies. **AHIP urges the Departments to grant good faith reporting relief for the entirety of the June 2024 reporting, but if full relief is not possible, we highlight specific areas where such relief is most needed.**

Timely Reporting Guidance and Updates to RxDC Reporting Instructions
AHIP appreciates the earlier release of the proposed Reporting Instructions for this year compared to the previous year. However, as in previous years, AHIP requests the Departments finalize and publish all future Reporting Instructions or any future changes to the underlying regulations no later than six months before the reporting deadline. If significant changes are made to the structure of the reporting (such as realigning the content of the D and P files or adding data elements), AHIP requests those changes be finalized and published no later than one (1) year in advance of their implementation and the first submission allow for good faith compliance. Alternately, if delays in publishing guidance or updates are unavoidable, AHIP recommends the Departments use their enforcement discretion to delay the reporting deadline for that year to a date no earlier than six months from the date the updates or guidance is released.

Data owners and reporting entities need to compile data files and then provide them to issuers, plan sponsors, TPAs, or other downstream entities to incorporate into filings or into merged data files passed to downstream entities. Data may need to be shared multiple ways across vendor relationships. The brief window of time would not allow adequate time to vet requirements, design, code, test and implement changes.

Changes to Data Aggregation Requirements and Enforcement
The proposed Reporting Instructions note that the RxDC collection of data from the 2023 reference year will include enforcement of the aggregation restriction, meaning that the data submitted in files D1 and D3 – D8 must 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. Practically, this means that when multiple reporting entities submit D2 data on behalf of the same plan, the reporting entity that submitted D2 at the most granular level will determine the aggregation level for compliance purposes. In other words, every reporting entity will need to know the aggregation level being submitted by every other entity, identify which is aggregating at the most granular level, and alter their reporting to match.

AHIP members are extremely concerned about being able to discover this information from plans' other vendors, particularly in the short four-month timeframe created by the January 31 release of the proposed Reporting Instructions. As we have noted previously, the Departments could address this visibility issue and reduce administrative burden by allowing reporting entities to submit all of their data aggregated at the state and market level. Reporting at these higher levels will reduce the burden on entities that must report on behalf of multiple entities while still allowing the Departments to detect significant trends with respect to prescription drugs that are increasing consumers' premiums and out-of-pocket costs.

Prior Year Data Reporting

AHIP members have shared that the additional detail required for reporting information in the prior year columns in D5 and the restated rebate columns in D6, D7, and D8 will increase their reporting burden. This concern also applies to the added corresponding instructions clarifying how to represent plans in P2 when the plan contributes to the prior year and restated fields but not to the current year fields (Sections 4.2, 8, and 9). Requiring additional information for termed plans from the prior year will create new work for plans and increase reporting burden.

Additionally, AHIP members have shared their concerns with the instructions included on pages 13, 16, and 21:

> **Note 1:** If a plan is included on the plan list solely because it contributed to prior year columns (D5) or the restated rebate column (D6, D7, D8) but didn't contribute to fields for the current reference year, report 01/01/2023 and 01/02/2023 as the plan year beginning and end dates, respectively.

These instructions, in which these plans are to be identified with "default" date values that are within the realm of possibility, conflicts with data integrity best practices. In this scenario, reporting entities are being asked to "manufacture" inaccurate dates that may conflict with actual dates. It would be possible for some plans to have been active for this specific 2-day period in 2023 and would cause confusion. AHIP encourages the Departments to consider alternative approaches, such as adding a "prior year costs/restated rebates only" indicator column to P2, assessing the use of the actual prior year dates, or designating null values for the dates for this scenario, which if used in conjunction with the Reference Year the P2 report is associated with, should provide a means for the Departments to achieve their objective.

New Requirement to Report Rx Enrollment in D6

As with the changes to data aggregation, AHIP members are concerned about the feasibility of implementing this change within the four-month period between the release of the proposed Reporting Instructions and the due date for submission of the data. In addition to sharing the concerns related to timely implementation, we are seeking clarification on the calculation of member months and the appropriate member inclusion methodology. We also highlight that the

new required column is not included in the D6 table on page 66 of the proposed reporting instructions. Because of these outstanding questions and concerns, AHIP recommends the Departments defer enforcement for the reporting due on June 1, 2024.

Form 5500
AHIP members continue to raise concerns about ensuring the correct Form 5500 number is reported, as this is not information received or stored by TPAs and issuers and the form may be filed up to seven months after the end of the plan year (or longer if an extension is granted). As the RxDC reporting is due on June 1, our members are concerned that the numbers they include in their reporting may not match what the employer ultimately reports on the form. AHIP supports flexibility in use of a unique group health plan number, such as capturing the federal employer identification number (FEIN), without a requirement to include Form 5500 numbers.

Premium Amounts Paid by Employers and Members
As part of the RxDC reporting, plans and issuers are required to report the average monthly premium amounts paid by the employer and the member. As we noted in our comments to the Departments in July 2021 (in response to the request for information), in January 2022 (in response to the interim final rules with request for comments and the associated PRA package), in July 2022 (in response to the PRA package), and in May 2023 (in response to the PRA package), AHIP members continue to express concern over the collection and reporting of this information. In response to the instructions from the Departments that this information is required for the June 2023 reporting, AHIP members undertook significant outreach to their employer clients to request this information, but primarily received no response from employers (particularly small employers and employers that have ended a contract with a reporting entity) or received information that is clearly incorrect (*e.g.*, the sum of the employer and member premium amounts does not equal the total premium amount).

For the current reporting year, AHIP members have shared that, while responses from employers have improved, there remain those who do not respond. Further, we are hearing reports from AHIP members that they are getting pushback from groups (Association Health Plans – AHPs – in particular) on the requirement to submit actual paid premium by each sub-employer. In the past, issuers could have estimated these premium amounts based upon Group Master Application information (*e.g.*, contribution percentage reported), but with the clarifications made within the new reporting instructions, issuers must now ask for the specific amounts paid by groups on behalf of their employees. This is a new and unique situation, where an issuer's compliance hinges upon information that the employer holds and to which the issuer has no access without the employer directly providing it.

AHIP requests that the Department clarify that this requirement does apply to both the AHP and the issuer and provide clearer instructions for situations where groups refuse to provide the information to the issuer. As the reporting requirement falls on both the issuer and the group, it

puts the issuer in the position to be liable for information that the group refuses to provide to the issuer or to the Departments. AHIP further recommends a safe harbor for this reporting year to avoid a frantic, last-minute submission of this information from groups to issuers (when issuers would not be able to reprocess their submissions to include the information) and allow for better communication in preparation for the reporting due on June 1, 2025.

Technical Assistance Webinars
AHIP appreciates the planned technical assistance webinars, though we were disappointed that there was not widespread communication about them. In prior years, these webinars have been a welcome resource for our members, and we appreciate the time and effort from Department staff to answer stakeholder questions. In the future, we urge the Departments to hold webinars beginning 5-7 business days after new Reporting Instructions are released to review details and discuss specific scenarios and subsequent impact.

Additional Requests for Clarification
In addition to our broader comments, AHIP requests clarification on the following items:

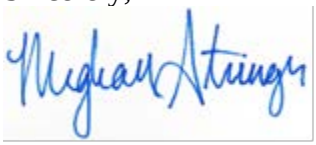
- **Calculation of average monthly premium.** The change to simplify the calculation of average monthly premium to use total annual premium divided by 12 instead of the average monthly premium on a per-member basis could lead to misleading numbers when there is less than 12 months-worth of premium data. Perhaps the Departments recognize this, but we wanted to flag it.
- **Carve-out description options.** We request clarification on the listing of medical benefits as a separate carve-out. As medical remains a majority share of administered benefits but is listed as an option, is the expectation to include "medical" in this field any time a group carves out a benefit even if the reporting entity is reporting on the majority of benefits? This question references page 15 of the proposed Reporting Instructions, where the following information on the data field is shared:

> Carve-Out Description
> **Location:** P2 Column C | **Max length:** 2,048 characters
>
> This field is required when a reporting entity is submitting data for a carved-out benefit and a different reporting entity (or entities) will report on the majority of the plan's other benefits. A carve-out benefit is a benefit administered, offered, or insured by an entity that is different than the entity that administers, offers, or insures the majority of the plan's other benefits.
>
> Enter one of the following:
> - Pharmacy only
> - Medical only
> - Behavioral health only

    - Fertility only
    - Specialty drugs only
    - Hospital only
    - Other
- **Timeline for Updating Crosswalk and Data Validations.** The last update to the "RxDC drug name and therapeutic class crosswalk" and the "RxDC data validations" documents were made in March 2023. Will there be annual updates of these documents, as with the Reporting Instructions? Or will updates for these documents occur only on an as-needed basis?

AHIP appreciates the opportunity to provide feedback on the collection of Prescription Drug and Health Care Spending data. If you have any questions or need additional information, please contact Meghan Stringer at mstringer@ahip.org. We look forward to continuing to engage constructively on these issues with the Departments and OPM as you continue work to lower health care costs for the American people.

Sincerely,



Meghan Stringer
Vice President, Product & Commercial Policy

April 1, 2024

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS–10788 Prescription Drug and Health Care Spending Report Instructions

Dear Sir/Madam:

UnitedHealthcare (UHC) is submitting comments to the Centers for Medicare & Medicaid Services (CMS) in response to an Information Collection Request (ICR) soliciting feedback on updates to the instructions for submitting the annual Prescription Drug and Health Care Spending Report (RxDC Report). The ICR was published in the Federal Register on January 31, 2024 (89 FR 6118).

UnitedHealthcare offers a full range of health benefits, enabling affordable coverage, simplifying the health care experience and delivering access to high-quality care. UnitedHealthcare is the health benefits business of UnitedHealth Group, a health care and well-being company working to help build a modern, high-performing health system through improved access, affordability, outcomes and experiences. We are committed to a future where every person has access to high-quality, affordable health care and a modern, high-performing health system that reduces disparities, improves outcomes, and lessens the burden of disease.

UHC appreciate CMS' efforts to work with stakeholders to streamline the RxDC reporting process. We offer recommendations below on additional improvements to the draft instructions.

Timing for Releasing Instruction Updates

The RxDC report is due no later than June 1 each year for the prior "reference year" data. We recommend that going forward, CMS release any final updates to the RxDC report instructions approved by the Office of Management and Budget (OMB) no later than December 31 of the reference year. We note that the "draft" instructions dated January 2024 have been posted on the CMS website as the "final" version that should be used for reporting Reference Year 2023 data. However, as stated in the ICR, "(u)nder the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor." (89 FR 6118). While UHC will use the January 2024 instructions for reporting 2023 Reference Year information, this draft version is currently open for public comment and has not yet been approved by OMB. Until final instructions are approved by OMB, there is a possibility reporting entities will face challenges determining which version should be used to submit the RxDC report.

In addition, as CMS is aware, group health plan service providers typically report on behalf of the plan. UHC sends an annual survey to plan sponsors soliciting information needed to complete the RxDC report. Finalizing the instructions no later than December 31 of the Reference Year allows service providers sufficient time to request the right information from plan sponsors. For example, the January 2024 draft instructions changed the method for calculating average monthly premiums and made other modifications that needed to

be reflected in the survey UHC sent to the sponsors of our employer group plan clients. Sufficient advance notice of the final instructions as approved by OMB allows UHC and other service providers to accurately define the data elements needed from plan sponsors in order to complete the RxDC report.

UHC recommends CMS obtain OMB approval and publish any final updates to the RxDC report instructions no later than December 31 of the Reference Year for the report.

Reporting Information on Behalf of Group Health Plans

We appreciate the recognition by CMS that multiple service providers may report data on behalf of a single group health plan. However, given employer groups are still learning these new requirements, it directly impacts UHC's ability to gather the D1 Average Monthly Premium Paid information and other ancillary data from employer groups needed to correctly populate the P2 Data File. We recommend CMS provide an enforcement safe harbor and permit reporting entities to leave portions of a report blank if they are unable, after a good faith effort, to collect relevant and/or accurate data from a plan sponsor.

UHC recommends CMS allow reporting entities to leave sections of a data file blank if they were unable to obtain relevant and/or accurate data from a plan sponsor after good faith efforts to collect the information.

Determining the "Majority" Benefits

The P2 Data File requires a "carve-out benefit" field (e.g., medical only, pharmacy only, behavioral health only). The instructions describe such benefits as follows:

> This field is required when a reporting entity is submitting data for a carved-out benefit and a different reporting entity (or entities) will report on the majority of the plan's other benefits. A carve-out benefit is a benefit administered, offered, or insured by an entity that is different than the entity that administers, offers, or insures the majority of the plan's other benefits.

(RxDC Report Instructions, January 2024, p. 15, *emphasis added*).

The term "majority" is not defined and further, a reporting entity may not be aware of other service providers for the group health plan. As a result, it is unlikely any single service provider will know who would be considered the entity administrating, offering or insuring "the majority of the plan's other benefits." While UHC agrees that a carve-out benefit field is appropriate, we believe the definition in the instructions should be revised to remove any reference to a majority of the plan's other benefits. Service providers should be required to designate the type(s) of benefits provided to the plan that are included in the RxDC report without having to understand or consider what other types of benefits may be offered.

UHC recommends CMS modify the report instructions to remove any reference to "the majority of the plan's other benefits."

We appreciate your consideration of UHC's comments. Please feel free to contact me if you have any questions.

Sincerely,

Tom Wilder

Tom Wilder
Director, Regulatory Affairs
UnitedHealthcare

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 Act[1] 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.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

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