June 20, 2024

Part D Plan Reporting Requirement Comment Submission

To whom it may concern,

My name is Michelle Juhanson, and I am submitting a comment on behalf of Pharmaceutical Strategies Group. PSG is a trusted advisor to health plans (including commercial, Medicare, Medicaid, and others), employers, and pharmacy benefit managers (PBMs). We work to help reduce pharmacy costs, optimize benefit designs, and protect the interests of plan participants. The Medicare Prescription Payment Plan (M3P) is a significant focus area for our Medicare clients, and it has the potential to improve the lives of many Medicare beneficiaries. We have reviewed the draft Part D Reporting Requirements for "Section VII. Medicare Prescription Payment Plan" and offer comments we believe will assist sponsors in reporting the information accurately for this new and essential Medicare benefit.

Likely to benefit identification

We recommend revising Report Element A, "Likely to Benefit Identification." The draft report states," The total number of individuals identified as likely to benefit from the Medicare Prescription Payment Plan during the reporting period based on one or more of the following methods." We recommend a change to "The total number of individuals identified as likely to benefit from the Medicare Prescription Payment Plan during the reporting period based on a summary of all the following methods: prior plan year criteria; during the plan year criteria; POS criteria. . ."

The current wording of Element A could lead to misinterpretation, as some may think that CMS is offering a choice of 'one or more of the following methods.' Divergent interpretations could result in inconsistent data reporting, significantly impacting the reliability of data across all plan sponsors. It's imperative to avoid such risks and ensure accurate data reporting.

As written, confusion with Element A can cause inconsistency in Element E, which states, "Among individuals identified in element A, the total number of those individuals who submitted an election request to participate in the Medicare Prescription Payment Plan during the reporting period." For example, ABC health plan follows the current instruction in A, and chooses only to include" prior plan year criteria." ABC health plan would underreport the total number of enrollee M3P elections because they would not count enrollee elections attributed to "during the plan year" and "POS criteria." To imagine the impact to data

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reliability, multiply the total number of plan sponsors by possible combinations of "one or more of the following" criteria to be reported.

CMS reporting typically prescribes what data should be included and excluded. We request CMS revise the report to follow this approach.

There is also a concern for future CMS oversight efforts, including Part D Program Audits and Part D Data Validation reporting. The data validation audit aims to have plan sponsors pay third parties to validate the underlying report methodology because CMS relies on plan-reported data as does the public.

Unsettled Balances

CMS has a December 31 cut-off for M3P reporting. However, billing procedures are in arrears. CMS risks losing collection activities that plans may need to pursue into the next plan year. Specifically, MMP amounts charged in October - December may be subject to a grace period and or in-cycle collection that stretches into the following plan year. CMS will not have an accurate picture of the monies owed to the plans because of unpaid M3P balances.

The reporting period is 1/1/2025 - 12/31/2025. December 2025 billing would occur in January 2025. A 45-day grace period would stretch into March or April billing, depending on the billing date.

Would CMS clarify if the intent is to collect data for events that have occurred as of 12/31/2025, or if the intent is to cover results for M3P claims/ M3P payments due through 12/31/2025, even if the billing and collection period are past 12/31/2025?

We recommend that the reporting dates do not align with accurate reporting for unpaid M3P balances. However, CMS has Direct and Indirect Remuneration (DIR) reporting, which is better suited to capture payment information because of its June deadline, and also because M3P payments are not reported on prescription drug events (PDEs). Money collected by the plan and not reported on a PDE generally meets CMS' definition of DIR. Similar to the DIR report for manufacturer rebates, CMS could allow plans to report the unpaid balances "expected but not received" through the DIR reporting period. There is also a mechanism in annual DIR reporting to revise prior year reporting data.

Like other DIR-reported data, PSG anticipates that CMS would consider M3P payments within the scope of the One-Third Financial Audit process versus the Part D Data Validation Audit. CMS One-Third Financial Audit contractors are accounting firms with the expertise to evaluate financial transactions. Firms with technical experience conduct the Part D Data Validation Audit process to evaluate the accuracy of reported data. Since the inception of the data validation audit process, CMS has not required plan sponsors to hire third-party auditors with accounting and financial reconciliation experience. We urge CMS to consider that elements A-K of the M3P report are well-suited to the Part D Data Validation Audit process. On the other hand, elements L-O better align with a financial review. For the reasons above, we request that CMS strike

the four elements under "Unsettled balances" from the Part D Reporting Requirement process and move them to the DIR report.

Thank you for taking the time to consider PSG's comments. We are available to discuss further and support CMS in developing future reporting requirements.

Sincerely,

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