January 9, 2023

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Mr. William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
U.S. Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Agency Information Collection Activities: Submission for OMB Review; Comment Request, CMS Plan Benefit Package (PBP) and Formulary CY 2024 [Document Identifier CMS–262-R]

Dear Mr. Parham:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the information collection review (ICR) issued by the Centers for Medicare & Medicaid Services (CMS) entitled: "Agency Information Collection Activities: Submission for OMB Review" as published in the *Federal Register* on November 9, 2022.[1] The ICR's subject is proposed revisions to the CY 2024 Plan Benefit Package (PBP) and formulary input tool.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and plans offered for sale on the exchanges established by the Affordable Care Act (ACA).

A. Changes to the PBP to reflect 2023 updates

We appreciate the efforts by the CMS and the Office of Management and Budget to update the CY 2024 PBP input tool. CMS's update is retrospective in part, given the several changes incorporated into the Part D benefit for plan year 2023 by Congress in the Inflation Reduction Act of 2022 (IRA).[2] This law was enacted after the 2023 PBP design process had concluded, after bids for plan year 2023 had been submitted, and after approved PBPs had been entered by participating Part D plans.

[1] 87 Fed. Reg. 67692 (November 9, 2022)
[2] Public Law 117-169 (August 16, 2022)

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The IRA includes two main provisions affecting Part D benefits for 2023. First, it requires plans to cover without cost sharing all adult vaccines recommended by the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). Second, it requires plans to provide all covered insulins at no more than $35 per month's supply including during a plan's deductible phase. **Overall, PCMA supports CMS's inclusion of these changes in the 2024 PBP to accomplish these updates in a uniform way across participating plans.** We have one clarifying question, regarding the requirement that Part D plan sponsors will be required to complete an attestation regarding the requirement to offer ACIP-recommended adult vaccines at $0 cost sharing. If there are plans that currently have a 7-tier formulary and don't have a vaccine $0 tier in 2023, if they need to add a vaccine $0 tier in 2024, will they be allowed to have 8 tiers? If an 8th tier is not allowed, can CMS please provide guidance on how existing plans are expected to shift their tiering structures?

B. Changes to the PBP for 2024 plan year statutory changes

Beginning in 2024, the IRA also limits cost sharing to 0% during the Part D benefit's catastrophic phase beginning in 2024. We provide comments below on CMS's proposed updates to reflect these changes. Since the 0% coinsurance applies to covered Part D drugs, it is not clear whether cost sharing on non-Part D covered drug benefits is also capped at 0% for catastrophic coverage in 2024. **PCMA recommends that CMS ensure that Appendix C-Rx is updated to accommodate the 0% cost-sharing entries.**

As a more matter of course change, CMS's proposed 2024 PBP input tool no longer includes Type 2 quantity limits. On page 6 of the Appendix B list of changes, and pages 1-2 of the Appendix C formulary submission file layout, CMS has proposed to remove the "Type 2" quantity limit. This change eliminates a way in which plans can communicate necessary details of such edits. The Type 2 QL allows plans to communicate with CMS that a limit is going to apply for a defined number of units over a set period. Our members report that this edit isn't used often but is usually for drugs that are either used short-term (Xifaxan 200 mg for traveler's diarrhea) or where a limit may be given for a lifetime (Shingrix, Mavenclad). Without the ability to let CMS know how we are administering a quantity limit, the associated risk is auditors misunderstanding the limits and creating a finding where there isn't one. **PCMA recommends CMS reinstate Type 2 quantity limits for the 2024 PBP.**

C. Planning for plan year 2025 and 2026 statutory changes

In 2025, the Part D benefit will be changed significantly. The PBP input tool will need to change in many ways, as plans determine cost sharing in the new coverage period, accounting for manufacturer-paid discounts on brand drugs. In 2025, plans must also accommodate beneficiary opt-ins to monthly out-of-pocket limits. Further, in 2026 new rules for covering drugs with negotiated "Maximum Fair Prices" begin, and plans may need additional input fields to accommodate them. While changes for 2025 and 2026 may be out-of-scope for CMS's

proposed 2024 PBP updates, we recommend CMS keep these upcoming changes in mind when making any changes to the 2024 PBP.

Conclusion

In summary, PCMA generally supports CMS's proposed changes to the PBP input process for plan year 2024, including retrospective updates. We also recommend CMS starting early on the 2025 and 2026 PBP input tools given the significant changes each of these years. Finally, while we are not providing more specific comments on the fields, some of our PBM members may be providing further comments, largely focused on clarifications in how some of the fields should be populated. We appreciate your attention to their comments. Thank you in advance for your consideration of our request. If you need additional information, please contact me (tdube@pcmanet.org) or Jani Mukherjee (dmukherjee@pcmanet.org).

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

cc: Jani Mukherjee, PCMA