July 31, 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 & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Information Collection Request (ICR) for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10847, OMB 0938-NEW)

Dear Mr. Parham:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the information collection request (ICR) issued by the U.S. Centers for Medicare & Medicaid Services (CMS) titled: "Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)" as published in the *Federal Register* on July 3, 2023.[1]

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, and plans offered for sale on the Exchanges established by the Affordable Care Act. PBMs negotiate price concessions with manufacturers on their brand medications to improve the value of the Part D program. These price concessions reduce premiums for all beneficiaries and provide access to preferred drugs with reduced cost sharing. Negotiated drugs under the IRA will be priced no higher than the prices PBMs are already able to negotiate. We have an interest in ensuring that appropriate data points are collected by CMS and that manufacturers validate the data they are submitting. Additionally, CMS needs to coordinate with other federal agencies to crosscheck data as well. The goal is to make sure that beneficiaries are afforded the best price possible and that manufacturers do not find loopholes in the CMS program.

- **PCMA recommends that CMS should allow for a sufficient length of time for continued use of the finalized data elements prior to making any changes to the data submission process and or forms.**

Per the guidance, CMS will require manufacturers of selected drugs to submit manufacturer specific data as well as evidence on alternative treatments. We appreciate the examples and tables provided for all required data elements for initial price applicability in 2026. Specifically, we applaud the use of prepopulated tables and maximizing the use of an automated tool within an existing information technology system, the Health Plan Management System (HPMS), for

[1] 88 Fed. Reg. 42722, July 3. 2023.

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Primary Manufacturers to report these data. Additionally, future form modifications, additions, and clarifications are appreciated and hopefully will result in accurate and timely data submissions. As the program matures, these forms should be updated periodically as needed. However, initially CMS should allow for a sufficient length of time for implementation, use, and any necessary adjustments to the process.

- **PCMA appreciates CMS prepopulating data forms with selected drug information to prevent any confusion regarding formulations, dosage and strengths included for negotiation.**

A majority of the data proposed for collection are publicly available and can be found in drug approval focused United States Food and Drug Administration submissions and or National Institutes of Health grant related paperwork. This should facilitate data validation and reduce confusion, especially since CMS is proposing to prepopulate the HPMS with the Dosage Form, Strength, Unit, and Labeler Code for each NDC-11 of the selected drug, including any NDC-11s that are marked as "discontinued." We recommend that CMS consider data use agreements or memoranda of understanding with other agencies, given that doing so will expedite future years' work and allow CMS to more efficiently determine appropriate maximum fair prices.

- **PCMA recommends that CMS not delay the availability of the online submission tool for the public at large. Additionally, PCMA supports CMS's efforts in promoting public access via e-mail submissions based on timing of the public tool launch date.**

In addition to manufacturer submissions, CMS is allowing for the general public to submit information and responses to sections I and J of this ICR via a publicly available web link. The web link is expected to be available after September 1, 2023 for initial price applicability year 2026. The online tool will allow for submissions related to Section I which addresses alternative treatments and allows for the public's perspective with regards to conditions covered by the negotiated drugs and patient's preference and or options for treatments. We recognize that September 1, 2023 is fast approaching and applaud CMS's proposal to allow for e-mail submissions in case of a delay in launching the public tool.

Conclusion

We hope CMS appreciates the discussion in this letter, from an interested industry stakeholder, as it looks to finalize key details of the Negotiation Program. It is critical to the PBM industry that data submitted by manufacturers to CMS be meaningful and interpreted and used in a way that helps achieve CMS's aims. Additionally, CMS's goals should include making sure the public feels fully engaged and that the data received by CMS is subject to the least amount of interpretation as possible. If you have any questions on these suggestions and recommendations, please do not hesitate to contact me directly at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs