August 24, 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) Form for Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10849, OMB 0938-NEW) ("Counteroffer form")

Dear Mr. Parham:

On July 25, 2023, the Centers for Medicare & Medicaid Services (CMS) announced in the *Federal Register*[1] an Information Collection Request (ICR) Form, as required by the Paperwork Reduction Act (PRA), for Negotiation Data Elements[2] under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). This ICR follows final guidance published by CMS in which it describes the negotiation process for selected drugs, among other topics ("the final guidance").[3] Our comments below discuss the two topics we raised in our initial letter on this matter.

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 can be priced no

[1] 88 Fed. Reg. 47880, July 25, 2023.
[2] CMS. "Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)." Available at https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.
[3] Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026. June 30, 2023. Available at https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

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higher than the prices PBMs are already able to negotiate.[4] We have an interest in ensuring that manufacturers do not find loopholes in the CMS program, so that Part D plans and their contracted PBMs have certainty as we continue to negotiate on behalf of the program for drugs not selected by CMS. Our comments below address both fields of the draft data collection form.

1. **We Thank CMS for Expanding the Length of Manufacturer Submissions in Response to Initial Offers**

Per the negotiation program guidance, CMS will allow manufacturers of selected drugs to submit a written counteroffer within 30 days of receipt of CMS's initial offer. CMS would receive written counteroffers from Primary Manufacturers through the Health Plan Management System. The counteroffer must provide a price per 30-day equivalent for the drug and respond to CMS's written justification for its initial offer. While initially offering only 1,500 characters and no ability to attach documents, under the revised counteroffer forms, manufacturers can now provide up to 2,500 words and attach up to ten documents. **We greatly appreciate CMS's willingness to entertain more voluminous responses from manufacturers. Taking more input from the public is never the wrong approach.**

2. **CMS Should Consider Receiving Counteroffers at the NDC-11 Level**

As described in CMS's final negotiation program guidance, qualified single source drugs include all dosage forms and strengths of the underlying active moiety. For its initial offer, CMS will provide its price for each National Drug Code (NDC)-11 offered for sale by the primary and any secondary manufacturers. This was not the initial starting point for CMS; originally CMS would have required manufacturers to populate their own list of NDCs. This change came about in response to public comments on a different ICR, including ours, noting that NDCs are registered by the Food and Drug Administration, and CMS should use external, validated partner agency data wherever possible.[5] **We wish to reiterate our recommendation that the counteroffer form under consideration here should also be accompanied by a pricing sheet from the primary and secondary manufacturer, the counteroffer price for each of its NDC-11s.** By requiring the manufacturer to provide the expected pricing for each package, there will be no miscommunication about 30-day equivalent pricing.

[4] SSA 1194(c) defines the price floor and price ceiling as the lower of average enrollment weighted net price of the selected drug, and a time-based calculation based upon its non-Federal Average Manufacturer Price (non-FAMP).

[5] See revised forms available at https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847. On page 4, CMS writes in part, "In Section A, for each selected drug for initial price applicability year 2026, CMS will populate the CMS HPMS with the list of the 11-digit National Drug Codes (NDC-11s) marketed by the Primary Manufacturer and any Secondary Manufacturer…"

Conclusion

We appreciate CMS's consideration of public comments in its moves toward finalizing critical documents and processes for the selection and negotiation of drugs under the multifunctional dual drug-loaded nanoparticle (MDNP). We hope our suggestions help CMS finalize data elements to be collected from manufacturers, 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