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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: Agency Information Collection Activities: Proposed Collection; Comment Request, [Document Identifier CMS–10844]

Dear Mr. Parham:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the notice with comment period issued by the U.S. Centers for Medicare & Medicaid Services (CMS) titled: "Agency Information Collection Activities: Proposed Collection; Comment Request," as published in the *Federal Register* on April 24, 2023.[1] This notice serves as the second draft of forms as part of this Information Collect Request (ICR) related to the Inflation Reduction Act's (IRA) drug negotiation provision. Through this ICR, CMS will finalize the information that pharmaceutical manufacturers would submit to justify an exception from being selected for negotiation due to being a "small biotech drug." The exception will apply for price applicability years 2026, 2027, and 2028. Additional CMS guidance on this provision was published elsewhere.[2]

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

[1] 88 Fed. Reg. 24805, April 24, 2023.
[2] CMS, "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments." Available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf. March 15, 2023. CMS encouraged policy comments regarding the small biotech provision to be submitted on the small biotech ICR, rather than the guidance.

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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 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.

We appreciate the changes CMS made to the data collection forms, including the addition of questions regarding active moiety or active ingredient to better assist CMS in identifying the applicant's product. We look forward to CMS's evaluation of our policy concerns, briefly restated and reaffirmed where applicable below.

- The changes made to the form to collect New Drug Application (NDA) and Biologic License Application (BLA) information still do not address a significant loophole where a primary manufacturer holds the NDA or BLA but has licensed the sales and marketing of the drug to a secondary manufacturer.
    - CMS should rely on the definitions of "primary manufacturer" and "secondary manufacturer" defined elsewhere in the guidance to help determine whether a drug should receive the exclusion. Conformity across the IRA's provisions will aid CMS in most efficiently designing and implementing this complex law.
    - In doing so, CMS should include additional questions on the form to determine which entity is marketing the product, receiving the revenue from its sale, and other arrangements under licensing agreement. We think this will help to limit the situations where one company holds the NDA or BLA but another company receives the revenue, allowing secondary manufacturers to benefit directly.
    - In the example below, the primary manufacturer – the company that holds the NDA or BLA – is not the entity that is physically selling the product in the market. In this case, the secondary manufacturer (a larger company) is benefitting from the primary manufacturer's potential exclusion of its drug for 2026, 2027, and/or 2028. The secondary manufacturer of *this* drug also has a drug that could qualify as a small biotech drug. However, when total spending for these two drugs (and others that the secondary manufacturer sells) is added together, *neither* drug would qualify under the terms of the exclusion, which we think is the appropriate outcome. (See Table 1.)
    - While the risk of this situation occurring is low (we found one potential situation that triggers the exclusion for two drugs in our analysis), primary manufacturers may view "selling" their Small Biotech Exclusion status for a licensing deal to a larger company as a potential windfall, to the detriment of Medicare beneficiaries and the Medicare program.

- The statute and guidance's definitions leave CMS vulnerable to excluding drugs that a reasonable person would not categorize as coming from a "small biotech" company.
    - Potential remedies for overinclusion of "not small" manufacturers include aligning with the U.S. Small Business Administration's or the Office of Management and Budget's definitions of "small businesses" for purposes of regulatory relief for these manufacturers.

- The statute would seem to provide significantly more protection to manufacturers of Part B products, based on a ceiling of 1% of spending under "such Part," than it does for manufacturers of Part D drugs.[3] Instead, CMS should use its authority to combine spending under Parts B and D when determining the 1% threshold with regard to the inclusion criteria for "small biotech drugs."

- The statute and guidance seem to infer that manufacturers of qualified single source drugs (QSSDs) only produce other brand drugs.
    - Several potential "small biotech drugs" are brand name products sold by manufacturers with diversified portfolios of brand, generic, and authorized generic products. Because pricing for authorized generic and generic products are significantly lower than for brand products, these manufacturers are more likely to have brand products excludable as "small biotech." CMS could adjust its 80% spending threshold to 80% of spending **or** claims volume for the manufacturer's product. This would ensure that companies that produce high volumes of commodity generics do not claim an unreasonable exception.

- The statute and guidance do not seem to recognize that a given product may be used more heavily outside of the Medicare program.
    - For example, there is a drug indicated for the treatment of cystic fibrosis, with about $6 billion in total US sales in 2021. It represents most of the primary manufacturer's spending in the Medicare program but that spending is less than 10% of the product's US sales. It is not eligible for negotiation until 2029, but were it eligible, it could be excluded as a small biotech drug.
    - To guard against unreasonable claims for small biotech exclusions, CMS should include a minimum percentage of total product revenue that Medicare spending reflects – maybe 33% – so that only "small biotech drugs" whose Medicare utilization generates a significant portion of a company's total revenue are excludable.

[3] To qualify for the exclusion, a drug must have Medicare Part B or Part D revenue of less than 1% of program spending. In 2028, for example, we estimate this would mean Medicare Part B spending up to $361 million, or spending as high as $2.5 billion in Part D.

Conclusion

CMS's goal in establishing this exclusion should be to gain the public trust that only true "small biotech" drugs are exempt from the negotiation process. We hope CMS appreciates the discussion in this letter, from an interested industry stakeholder, as it looks to finalize key details. It is critical to the PBM industry that pharmaceutical manufacturers are not able to identify loopholes and "save themselves" from direct negotiation. We hope our suggestions help CMS narrowly define the limited and narrow small biotech drug exclusion for 2026, 2027, and 2028. 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

Attachment: Table 1

Table 1: Example of a Primary and Secondary Manufacturer Licensing Deal Generating Two Small Biotech Exclusions (SBE)[4]

Based on Current Guidance Attributing Spending to only the NDA/BLA Holder		Proposed Aggregation to the Secondary Manufacturer
• **Product A** generates $600-$700 million in Part D spending, accounting for 100% of **Company A**'s Medicare spending as the NDA/BLA holder. It is excludable under the SBE. However, **Company B** markets the product and receives all revenues, paying a share to Company A through a licensing agreement.	• **Product B** generates $800-$900 million in Part D spending, accounting for >80% of **Company B**'s Medicare spending as the NDA/BLA holder. It is excludable under the SBE.	• **Product A** represents 35-40% of **Company B**'s combined Medicare spending as a primary or secondary manufacturer and is **not** excludable under the SBE. • **Product B** represents 45-50% of **Company B**'s combined Medicare spending as a primary or secondary manufacturer and is also **not** excludable under the SBE.

[4] We do not have access to the specific months of spending data that CMS will use to create its list of negotiation eligible drugs. The actual companies and drugs eligible for the small biotech exception may differ from our findings. Therefore, we have removed specific identifying information, to make it more illustrative than a direct case study.