March 27, 2024

Administrator Chiquita Brooks-LaSure
CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10858
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via: www.regulations.gov

Re: Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (CMS-10858)

Dear Administrator Brooks-LaSure:

The Association for Accessible Medicines (AAM) appreciates the opportunity to provide comments in response to the *Proposed Collection Comment Request for Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (CMS-10858)*. AAM represents the manufacturers and distributors of finished generic and biosimilar pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generics and biosimilars industry.

Because of their low cost and high value to patients and payers, generic and biosimilar medicines today account for greater than 90% of all prescriptions dispensed in the US, but only 17.5% of prescription drug spending. In fact, generic medicines are less than 2% of total U.S. health care spending. The U.S. health care system has saved nearly $2.9 trillion in the last 10 years due to the availability of affordable generic medicines. In 2022, competition from generic medicines resulted in more than $408 billion in savings to the health care system, including more than $130 billion in savings for the Medicare program.[1]

CMS Should Partner with the FDA to Obtain Shortage Information to Reduce Duplicative Reporting

AAM supports the waiver and reduction of inflation rebates in the event of a severe supply chain disruption or a probable risk of shortage, as determined by the agency. We believe,

[1] Association for Accessible Medicines. (September 2023) The US Generic and Biosimilar Medicines Savings Report (Link)

however, that CMS's proposal to require manufacturers to submit requests for rebate reductions with supporting documentation may be duplicative of existing processes currently administered by the Food and Drug Administration (FDA), unnecessarily increasing the administrative burden on drug manufacturers.

In accordance with Sections 506C and 506E of the Food and Drug Administration's (FDA) Food, Drug, and Cosmetic (FD&C) Act, all manufacturers of covered and approved prescription drugs or biological products are required to inform the FDA of any manufacturing interruption for a product that could potentially lead to a significant disruption in supply. This mandatory notification process is designed to aid the FDA in complying with Section 506E of the FD&C Act, which requires the FDA to maintain a publicly available list of drugs in shortage. This list is required to provide: (1) the names and national drug codes (NDCs) of the drug or biological product in subject; (2) the name of the manufacturer; (3) the reason(s) for the shortage; and (4) the estimated duration of the shortage.

With respect to documenting existing drug shortages, we believe the information, found in the FDA's Drug Shortage Database, is sufficient for CMS to determine whether a severe supply chain shortage exist for the purposes of waiving the IRA inflationary rebate provisions. This information could easily be shared with CMS through a Memorandum of Understanding (MOU) with the FDA and could, at a minimum, help reduce duplication and the administrative burden placed on manufacturers in their reporting to CMS. We encourage the agency to leverage the FDA's existing tools for such determinations instead of establishing an entirely separate process for manufacturers to accomplish the same objective.

Additionally, the FDA monitors and actively works with manufacturers when there is a potential drug shortage. The FDA employs a Drug Shortage Staff (DSS) that resides in the Center for Drug Evaluation and Research (CDER). DSS consists of a dedicated staff responsible for the coordination of all activities related to the prevention and mitigation of drug shortages. These individuals monitor reports of potential and actual drug shortages to prevent products from going into shortage. We encourage CMS to partner with the FDA as it considers the information and documentation the agency needs to determine review rebate reductions requests.

CMS Should Provide the Forms on its Website to Improve the Proposed Submission Process

The CMS data collection proposal states, ""Within 5 business days of receipt, CMS will respond by providing the manufacturer with (1) a PDF of the rebate reduction request form (available as Appendix A, B, C, and D of this ICR), and (2) access to a Box folder, or similar secure file sharing management platform approved by CMS, specific to the manufacturer's request". In a situation where time is critical, this seems to introduce unnecessary delays. AAM recommends that CMS post the forms on their website such that the manufacturer could submit the forms with the initial email to CMS.

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CMS Should Provide Additional Clarity on Certain Aspects of the Rebate Reduction Process

The CMS data collection proposal states, "… when CMS determines the drug is likely to be in shortage during a subsequent applicable period." AAM requests additional clarity with respect to how CMS will make such a determination. For instance, as we suggested in our comments on March 11, 2023, it is not clear how CMS will approach rebatable products that are coming out of shortage. There is a risk that a manufacturer must take a price increase to help it recover from a drug shortage only to immediately incur a significant penalty the moment the FDA removes it from the drug shortage list. In fact, one of the predictors of a drug vulnerable to shortage is a previous shortage.

To address the challenge of recurring drug shortages, we recommend CMS treat generic drugs exiting a shortage as being at risk of shortage and provide for a transitional period of a gradually declining rebate reduction. For instance, for a drug in shortage with a full rebate waiver, CMS could phase out the penalty through a 25% reduction for each quarter after the shortage ends (75% in the first quarter, 50% in the second quarter, etc.)

To that end, the proposal states that CMS will "develop policies and procedures for determining whether to grant a request or deny a request". AAM recommends that CMS should clarify that it will provide notice and comment opportunity for these policies and procedures to ensure that they are appropriate.

The data collection proposal further states that "A business operations specialist, or team of business operations specialists … [will] … collect information and provide brief explanations detailing the specifics of the severe supply chain disruption or likely shortage, including determining changes in drug production and distribution and when supply is expected to meet demand. The business operations specialist, or team, will also submit information on how the manufacturer plans to resolve or mitigate the severe supply chain disruption or likely shortage." If a severe supply chain disruption is defined as including "disasters or other unexpected events, or other unique or unexpected events", manufacturers may not be able to submit information estimating when supply is expected to meet demand or other resolution or mitigation strategies relative to the timeframe provided by the process for requesting the reduction and submitting the (duplicate) information requested by CMS. Accordingly, AAM requests that the agency exercise discretion in the implementation of this requirement to reflect the uncertainty inherent in these situations.

CMS Forms Should Account for Secondary Manufacturers

CMS provided additional clarity with respect to the agency's interpretation of the term secondary manufacturer in the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (cms.gov). However, neither the underlying policy to waive and reduce inflation rebates in the event of a severe supply chain disruption or a probable risk of shortage, nor the data collection forms fully account for secondary / co-manufacturers and are thus misaligned

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with other CMS programs, including those enacted under the IRA, notably the Drug Price Negotiation Program. CMS should align operational policy, and the forms, to reflect the possibility for market dynamics that include secondary / co-manufacturers.

CMS Should Clarify Certain Aspects of its Burden Estimates

The data collection proposals estimate the agency will receive 10 rebate reduction requests / extension requests per year. There are many more than 10 drugs in shortage on FDA's drug shortages website. AAM requests clarity with respect to how the agency arrived at its estimate.

Additionally, the total burden calculations only seem to reflect the hourly rates required by one of the individuals mentioned in the estimate. In instances where there is a "team of" such individuals, the agency should include a multiplier. Accordingly, particularly for larger manufacturers, even for the "high estimate", it may be wholly inadequate to simply "double" the burden estimate, and a higher burden estimate may be appropriate.

AAM appreciates the agency's consideration of its comments and looks forward to continuing to serve as a resource for CMS.

Sincerely,

Craig Burton

Craig Burton
Senior Vice President, Policy & Strategic Alliances, AAM
Executive Director, Biosimilars Council

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