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Submitted electronically via: www.regulations.gov

March 29, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Deputy Administrator Seshamani:

Sandoz Inc. (Sandoz) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed new Information Collection Request titled “Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act” (ICR). Sandoz is a global leader in generic drugs and biosimilar products. Our purpose is to pioneer access for patients. We focus on driving access to make a difference for patients, working always with patients in mind. Our broad portfolio of high-quality medicines covers major therapeutic areas.

Sandoz is concerned that the ICR fails to address the relationship between primary manufacturers and secondary manufacturers, and how severe supply chain disruptions affecting either party may affect the drug's eligibility for exclusion from the Part B/D inflation rebate. While CMS recognizes and explains the distinction between primary and secondary manufacturers for purposes of administering the IRA’s Medicare Drug Negotiation Program (MDNP),¹ the agency neglects to include any similar analysis for the Part B/D inflation rebates. This creates an inconsistency in the agency's implementation policies for drug payment programs under its jurisdiction, and a significant data collection gap that affects the determination of whether a Part B/D drug qualifies for an exclusion from the inflation rebate requirements due to a shortage or likely shortage.

Therefore, we urge CMS to amend the ICR to allow information from both primary and secondary manufacturers to reflect situations that may affect different manufacturer's ability to seek an exemption from the Part B/D inflation rebates for the same product. This would

¹ Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (June 20, 2023).


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harmonize the agency's implementation of the MDNP with the Part B/D inflation rebates in terms of recognizing and accommodating the market realities of drug commercialization.

Sandoz also supports the views expressed in comments to this ICR submitted by both the Association for Accessible Medicines (AAM) and the Biosimilars Forum (the Forum). Sandoz appreciates the opportunity to comment on the ICR. We look forward to continuing to work with the agency to help ensure adequate access to affordable medicines for Medicare beneficiaries.

If you have any questions about these comments, please do not hesitate to contact Mary Jo Carden, Head of Policy, at mary_jo.carden@sandoz.com

Respectfully submitted,

DocuSigned by:

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Leslie Pott
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