DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: May 13, 2025

TO: Interested Parties

FROM: Christina Ritter, Director
Medicare Drug Rebate and Negotiations Group

SUBJECT: **Medicare Drug Price Negotiation Program: Drug Selection 60-Day Information Collection Request Published for Comment**

CMS announces the publication of an information collection titled the Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Redaction Act Information Collection Request (hereinafter, the "Drug Selection ICR"). The Drug Selection ICR can be found in the Federal Register. The full text of the ICR can also be found at CMS' PRA website. Comments are due by **July 14, 2025**.

This package contains three parts: 1) the *Small Biotech Exception*, which includes the information necessary for CMS to determine if a qualifying single source drug meets the requirements to be excluded as a negotiation-eligible drug upon request by the manufacturer of the drug, 2) the *Biosimilar Delay*, which includes the information necessary for CMS to determine if a biosimilar biological product (the "biosimilar") qualifies for a delay of inclusion as a negotiation-eligible drug upon a request by the manufacturer of such a biosimilar, and 3) the *Identification and Selection of Renegotiation-Eligible Drugs*, which includes a voluntary submission of data from Primary Manufacturers of selected drugs to inform CMS' determinations of which selected drugs qualify as a renegotiation-eligible drug and may be selected for renegotiation for initial price applicability year 2028.

Manufacturers requesting a small biotech exception or biosimilar delay will submit their information through the CMS Health Plan Management System (HPMS) website. Instructions to gain access to the CMS HPMS are available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.

Primary Manufacturers of selected drugs may voluntarily submit information to inform CMS' determination for renegotiation-eligible drug identification and selection through a specific Box folder, that CMS will make available, for each selected drug.