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DATE: January 13, 2025

TO: Drug Manufacturers

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

SUBJECT: Negotiation Data Elements and Drug Price Negotiation Process Information Collection for Initial Price Applicability Year 2027

The Negotiation Data Elements and Drug Price Negotiation Process information collection request (ICR) form for initial price applicability year 2027 is now final and available for viewing on OMB's [website](#) (CMS-10849, OMB 0938-1452).

The Inflation Reduction Act (IRA) of 2022 established the Medicare Drug Price Negotiation Program (Negotiation Program) to negotiate maximum fair prices for certain high expenditure, single source drugs. For the second year of the Negotiation Program, initial price applicability year 2027, CMS will select for negotiation up to 15 high expenditure, single source drugs covered under Part D.

This ICR addresses two components of the Negotiation Program. First, section 1194(e) of the Act requires CMS to consider two sets of factors as the basis for determining offer(s) and counteroffer(s) throughout the negotiation process: (1) certain data that must be submitted by the manufacturer of each drug selected for negotiation in section 1194(e)(1); and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug in section 1194(e)(2) collectively, (the "Negotiation Data Elements"). Second, in accordance with section 1194(b)(2)(C) of the Act, a manufacturer may submit an optional statutory written counteroffer (the "Counteroffer"), if CMS' written initial offer is not accepted by the manufacturer of a selected drug (the "Drug Price Negotiation Process").

Manufacturers of selected drugs that sign an Agreement with CMS will submit their information through the [CMS Health Plan Management System \(HPMS\) website](#) by March 1, 2025. Manufacturers may register for access to the CMS HPMS, and are encouraged to do so, before the questions for this ICR are available in the coming weeks. For additional information about CMS HPMS user access, please visit: <https://www.cms.gov/about-cms/information-systems/hpms/user-id-process>.

Members of the public may optionally submit evidence about alternative treatments in the coming weeks by March 1, 2025 via a web link that will be available through the [CMS HPMS landing page](#) and CMS.gov.

Additionally, the ICR describes the data and information the federal government will collect for consideration if a manufacturer of a selected drug submits a statutory written counteroffer for a selected drug during the negotiation process. For initial price applicability year 2027, CMS will issue an initial written offer no later than June 1, 2025 and statutory written counteroffers, if applicable, will be due 30 days after receipt of the initial offer.

For questions, please contact IRAREbateandNegotiation@cms.hhs.gov.