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DATE: January 12, 2026

TO: Drug Manufacturers and Other Interested Parties

FROM: Lara Strawbridge, Acting Director
Medicare Drug Rebate and Negotiations Group

SUBJECT: Drug Price Negotiation Information Collection for Initial Price Applicability Year 2028

CMS announces the approval of the Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (hereinafter, the “Drug Price Negotiation ICR”) (CMS-10849, OMB 0938-1452) by the Office of Management and Budget on January 12, 2026 (available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0938-003).

Under the Medicare Drug Price Negotiation Program (the “Negotiation Program”), CMS negotiates with manufacturers to establish maximum fair prices for certain high expenditure, single source drugs. For the third cycle of the Negotiation Program, initial price applicability year 2028, CMS will select for negotiation up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D and CMS will announce drugs selected for renegotiation, if any, by no later than February 1, 2026.

Manufacturers of selected drugs that sign an Agreement with CMS must submit their negotiation data elements information through the [CMS Health Plan Management System \(HPMS\) website](#) by March 1, 2026. Manufacturers must be registered for access to the CMS HPMS. 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 selected drugs and their alternative treatments by March 1, 2026 via a web link that will be available through the CMS HPMS webpage when the submission period begins: https://hpms.cms.gov/app/ng/pblc_cmt/.

CMS will notify manufacturers and the public when the submission period opens.

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