

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



CENTER FOR MEDICARE

DATE: November 7, 2024

TO: Drug Manufacturers

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

SUBJECT: Requesting a Small Biotech Exception or a Biosimilar Delay in the Health Plan Management System (HPMS) for Initial Price Applicability Year 2027

On November 8, 2024, CMS will release the functionality for manufacturers to request a Small Biotech Exception and a Biosimilar Delay in the CMS Health Plan Management System (CMS HPMS) for initial price applicability year 2027. Manufacturers seeking a Small Biotech Exception or a Biosimilar Delay must submit a Small Biotech Exception request or a Biosimilar Delay request in HPMS by **11:59 p.m. PDT on December 10, 2024**.

The Inflation Reduction Act (IRA) of 2022 establishes 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.

Section 1192 of the Social Security Act provides certain exceptions and exclusions for otherwise negotiation-eligible drugs. The submission of a request for a Small Biotech Exception or a Biosimilar Delay provides the information necessary for CMS to determine the applicability of two potential circumstances provided under the Act where certain drugs may be removed from negotiation eligibility if certain statutory requirements are met. Specifically, in accordance with section 1192(d)(2) of the Act, the term “negotiation-eligible drug” excludes, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the “Small Biotech Exception”). Additionally, in accordance with section 1192(f)(1)(B) of the Act, CMS may delay the inclusion of a negotiation-eligible drug that includes the reference product for a biosimilar biological product on the selected drug list for a given initial price applicability year if certain statutory requirements are met regarding the biosimilar’s status of licensure and marketing (the “Biosimilar Delay”) in accordance with section 1192(f) of the Act.

The Office of Management and Budget (OMB) approved this information collection request (ICR) (CMS-10844, OMB 0938-1443) on November 1, 2024 (available at:

https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202410-0938-001). The CMS HPMS functionality described above is the mechanism by which a manufacturer may respond to this ICR.

Instructions for manufacturers to gain access to the CMS HPMS are available at:

<https://www.cms.gov/about-cms/information-systems/hpms/user-id-process>. Manufacturers with access to the CMS HPMS will be able to access the functionality within the CMS HPMS to complete and submit a Small Biotech Exception request or a request for a Biosimilar Delay within CMS HPMS starting at 6 p.m. EST on November 8, 2024:

<https://hpms.cms.gov/app/ng/home/>.

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