



CENTER FOR MEDICARE

DATE: June 2, 2023

TO: Drug Manufacturers Interested in Submitting a Small Biotech Exception Request for Initial Price Applicability Year 2026 of the Medicare Drug Price Negotiation Program

FROM: Christina Ritter, Acting Director
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SUBJECT: Instructions for Requesting the Small Biotech Exception in the Health Plan Management System (HPMS)

On June 2, 2023, the Centers for Medicare & Medicaid Services (CMS) will release the Small Biotech Exception functionality in HPMS for initial price applicability year 2026 of the Medicare Drug Price Negotiation Program (“Negotiation Program”).

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), CMS is implementing the Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). In accordance with section 1192(d)(2) of the Act, the term “negotiation-eligible drug” excludes, with respect to the 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”).

In order to accurately identify, at the request of a manufacturer, whether a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 in accordance with section 1192(d)(2) of the Act, CMS needs to collect certain information as described in the Small Biotech Exception Information Collection Request (ICR) (CMS-10844¹, OMB 0938-1443).

OMB approved this ICR on May 26, 2023. This memorandum provides instructions for how to submit a Small Biotech Exception request for initial price applicability year 2026 of the Negotiation Program pursuant to this ICR, including the process for submitting such a request and next steps after submission.

For initial price applicability year 2026, the deadline for submitting Small Biotech Exception requests in HPMS is **11:59 p.m. PDT on July 3, 2023²**.

¹ https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202304-0938-016

To view the collection instruments, check “All” at the top of the page. Scroll down to the section “Number of Information Collection (IC) in this ICR” and click “Small Biotech Exception Information Collection Request Form” to access the form.

² Information on how to submit a Small Biotech Exception request for initial price applicability years 2027 and 2028 will be published in future guidance.

Instructions for Submitting a Small Biotech Exception Request

To request the Small Biotech Exception for a qualifying single source drug for initial price applicability year 2026, manufacturers must submit a Small Biotech Exception request via HPMS. Access to the Small Biotech Exception request functionality will be granted automatically to active manufacturer users in HPMS. Instructions for creating an account in HPMS are available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess>. Manufacturers should refer to the link entitled “Drug Manufacturer User ID EFI Instructions.”

Manufacturers can access the Small Biotech Exception functionality in the Drug Price Negotiation module in HPMS. This module will be available in HPMS on June 2, 2023. Instructions for accessing this module and completing a Small Biotech Exception request will be available on the HPMS landing page: <https://hpms.cms.gov/app/ng/home/>.

CMS will only accept submissions for Small Biotech Exception requests for initial price applicability year 2026 via HPMS, not via e-mail or any other format³. Because of the extremely tight statutory deadlines during the first year of the Negotiation Program, CMS will not accept incomplete or late requests for the Small Biotech Exception for initial price applicability year 2026.

Manufacturers must complete two steps in order to submit an exception request for initial price applicability year 2026:

1. Fill out the Small Biotech Exception online request form in the HPMS Drug Price Negotiation module
2. Complete the certification in HPMS in the HPMS Drug Price Negotiation module

The individual who certifies the submission in HPMS must be (1) the chief executive officer (CEO), (2) the chief financial officer (CFO), (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3). Instructions for individuals to gain signatory access to HPMS can be found in the May 4, 2023 HPMS memo entitled “Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS),” also available in the Downloads section at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess>.

CMS will allow manufacturers to revise their submission up until the deadline (11:59 p.m. PDT on July 3, 2023), even after they have completed the certification. Manufacturers will have to recertify their submission if they edit it after their initial certification. Manufacturers must both complete the form data entry and certify the completed form prior to the deadline in order for their request to be considered.

³ The Small Biotech Exception ICR stated that CMS would accept submissions via e-mail only in the event that the tool in HPMS was not ready in time; however, because the tool is available, CMS will only accept submissions via HPMS.

Requests for technical assistance can be directed to the HPMS help desk, available at hpms@cms.hhs.gov or 1-800-220-2028.

Communicating Results of the Small Biotech Exception

CMS will notify each manufacturer that submits a Small Biotech Exception request whether their drug received the exception for initial price applicability year 2026 in September, 2023. This communication will be sent by e-mail to the individual that completed the form data entry. CMS will publish the number of drugs that applied for and received the Small Biotech Exception for initial price applicability year 2026 as part of publishing the selected drug list on September 1, 2023.

For questions about this memo, please contact CMS at IRAREbateAndNegotiation@cms.hhs.gov with the subject line “Small Biotech Exception ICR Form Question.”

For technical assistance with HPMS, please contact the HPMS Help Desk at either hpms@cms.hhs.gov or 1-800-220-2028.