Supporting Statement – Part A

Small Biotech Exception Information Collection Request (CMS-10844, OMB 0938-NEW)

A. Background

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price 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").[1] Among other requirements for this exception, the statute requires that CMS consider, for Part D drugs, total 2021 Medicare expenditures for the drug under Part D; total expenditures for all covered Part D drugs for such year; and total expenditures under Part D for all covered Part D drugs for which the manufacturer has an agreement under section 1860D-14A during 2021.

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 information to identify the entity that had a Medicare Coverage Gap Discount Program Agreement under section 1860D-14A[2] for the drug as of December 31, 2021, including all other entities that, as of December 31, 2021, were treated as a single employer with that entity under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 and had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021. For the purpose of this information collection request, "controlled group" means all corporations or partnerships, proprietorships, and other entities treated as a single employer under 26 U.S. Code section 52(a) or (b).

Note: This information collection request does not collect all information that may be relevant to a manufacturer's request for the Small Biotech Exception for initial price applicability years other than 2026. For example, this information collection request does not collect all information relevant to the statutory limitation found in section 1192(d)(2)(B)(ii) of the Act (which precludes the application of the Small Biotech Exception to a qualifying single source drug if the manufacturer of that drug is acquired after 2021 by a manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii)) because the earliest effective date specified in that limitation (January 1, 2025) has no impact until initial

[1] For the purposes of this information collection request, qualifying single source drug has the same definition as it is given in section 30.1 of the Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments ("Initial Negotiation Program Guidance" – see https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf).

2 OMB control number: 0938-0982

price applicability year 2027 (the first initial price applicability year with a selected drug publication date after January 1, 2025). Additionally, this information collection request does not collect all information relevant to Part B drugs, as Part B drugs may not be selected for negotiation until initial price applicability year 2028, in accordance with section 1192(a)(3) of the Act.

A determination by CMS that a given qualifying single source drug qualifies for the Small Biotech Exception for initial price applicability year 2026 does not mean that this drug will continue to qualify for the Small Biotech Exception for future initial price applicability years. The process for submitting a request for a drug to qualify for the Small Biotech Exception for initial price applicability years 2027 and 2028 will be addressed in future guidance.

B. Justification

1. Need and Legal Basis

CMS currently does not have information necessary to determine whether manufacturers of Medicare Part D drugs and biological products were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code as of December 31, 2021. This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act. To ensure that only qualifying single source drugs that meet the requirements for the Small Biotech Exception are excluded from the term "negotiation-eligible drug," a manufacturer that seeks the Small Biotech Exception for its qualifying single source drug ("Submitting Manufacturer") must submit information to CMS about the company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the Small Biotech Exception for a qualifying single source drug it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021. The Information Collection Request Form for the Small Biotech Exception must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2026. The timeline for submission of this information will be provided in program instruction.

Manufacturers who might benefit from submitting a Small Biotech Exception request for initial price applicability year 2026 are those manufacturers of a qualifying single source drug who believe that (1) the drug meets the criteria for the Small Biotech Exception as set forth in section 1192(d)(2) of the Act and as described in the Initial Negotiation Program Guidance and (2) absent such a request, the drug will be considered a negotiation-eligible drug for initial price applicability year 2026 based on the criteria and process specified in section 1192(d) of the Act and the Initial Negotiation Program Guidance. As described in section 30.2.1 of the Initial Negotiation Program Guidance, to the extent that more than one entity meets the statutory definition of a manufacturer of a qualifying single source drug, only the holder of the New Drug Application(s) or Biologics License Application(s) for the qualifying single source drug may be the Submitting Manufacturer. In accordance with section 1192(d)(2)(C) of the Act, for purposes of applying the Small Biotech Exception, a qualifying single source drug may not solely consist

of a new formulation of another drug that is also considered a separate qualifying single source drug; consistent with section 30.1 of the Initial Negotiation Program Guidance, new formulations aggregated as part of the qualifying single source drug would not disqualify the qualifying single source drug from consideration for the Small Biotech Exception.

2. Information Users

The requirements for the Small Biotech Exception are specified in section 1192(d)(2) of the Act. When the Submitting Manufacturer completes the Information Collection Request Form for the Small Biotech Exception and submits the form to CMS, CMS will use the submitted information to inform the agency's consideration and determination of whether the Submitting Manufacturer's qualifying single source drug qualifies for the Small Biotech Exception. For example, CMS will use the submitted information to identify and verify the entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021, aggregate the appropriate expenditures under Part D, and assess whether the drug meets the statutory requirements for the Small Biotech Exception.

3. Use of Information Technology

CMS intends to develop an automated tool within an existing information technology system, the Health Plan Management System (HPMS), for manufacturers to submit the Small Biotech Exception Information Collection Request Form. Manufacturers of Medicare Part D drugs currently use this system for other Part D program needs. Instructions for manufacturers to gain access to HPMS can be found in the "Instructions for Requesting a New CMS User ID: HPMS Drug Manufacturer Users" PDF[3]. The new automated tool is scheduled to be available by mid-2023; in the event that its completion is delayed, CMS will accept responses to this information collection request by e-mail at IRARebateandNegotiation@cms.hhs.gov with the subject line "Small Biotech Exception Information Collection Request Form Submission." The individual who certifies the Submitting Manufacturer's submission in HPMS must be the (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 "Instructions for Requesting Electronic Signature Access in the Health Plan Management System (HPMS)" PDF.[4]

Completing this form requires the Submitting Manufacturer to provide the following information:

- Identifying information about the Submitting Manufacturer as of the date of submission, including the Submitting Manufacturer's name, Employer Identification Number(s) (EIN(s)), mailing address, the unique identifier(s) assigned by CMS to the Submitting Manufacturer (P-number(s)), and all labeler codes;

[3] https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/downloads/sysinstr-for-requesting-drug-manufacturer-access.pdf
[4] https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/downloads/syshpms-electronic-sign-memo.pdf

- Identifying information about the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception:
    - Active moiety (for drug products) or active ingredient (for biological products);
    - All New Drug Applications (NDAs) held by the Submitting Manufacturer for any drug products with the active moiety or all Biologics License Applications (BLAs) held by the Submitting Manufacturer for any biological products with the active ingredient; and
    - All 11-digit National Drug Codes (NDCs) for drug or biological products with the active moiety or active ingredient, as applicable, and marketed pursuant to any of the NDAs or BLAs identified in the previous sub-bullet, that were (A) sold or marketed during 2021 or (B) end-dated prior to December 31, 2021;
- Identifying information as of December 31, 2021 for the entity that had a Medicare Coverage Gap Discount Program agreement for the qualifying single source drug on December 31, 2021, and all members of that entity's controlled group that had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021; and
- A certification by (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 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).

4. Duplication of Efforts

The information collection does not duplicate any other effort, and the information cannot be obtained from any other source.

5. Small Businesses

This collection of information has been designed with a view towards minimizing the reporting burden for Submitting Manufacturers. The information is being collected once for initial price applicability year 2026 and only from the Submitting Manufacturer seeking the Small Biotech Exception for its qualifying single source drug and includes those data items necessary for CMS (1) to determine, as of December 31, 2021, the entities with a Medicare Coverage Gap Discount Program agreement that were treated as a single employer with the entity that had a Medicare Coverage Gap Discount Program agreement for that qualifying single source drug on December 31, 2021, and (2) to identify the applicable Medicare expenditures for purposes of implementing the Small Biotech Exception. In accordance with section 1192(d)(2) of the Act, the Small Biotech Exception applies to drugs for which 2021 Medicare expenditures meet the specified thresholds. Such drugs may be manufactured by entities that are considered to be a small business. The impacts of this collection on a Submitting Manufacturer are estimated to be the same regardless of the size of the Submitting Manufacturer.

6. Less Frequent Collection

Less frequent collection would not be an option because a Submitting Manufacturer is expected to submit the information only once per initial price applicability year for each drug for which the Submitting Manufacturer seeks the Small Biotech Exception.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

A 60-day notice was published in the Federal Register on January 24, 2023 (88 FR 4184). We received 6 public submissions of comments following the 60-day comment period.

The 30-day notice was published in the Federal Register on April 24, 2023.

A summary of comments received and CMS' responses, as well as a crosswalk describing the changes from the initial package to the current package, are also attached.

Outside Consultation
In the development of the Small Biotech Exception Information Collection Request Form, CMS sought input from other federal agencies. For example, the Internal Revenue Service (IRS) provided technical assistance related to subsection (a) and (b) of section 52 of the Internal Revenue Code of 1986.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for submission. If CMS determines that the Small Biotech Exception does apply for an initial price applicability year, then the qualifying single source drug for which the Submitting Manufacturer sought an exception will be excluded from the term "negotiation-eligible drug" for that initial price applicability year.

10. Confidentiality

All information collected will be kept private to the extent permitted under applicable laws and regulations.

11. Sensitive Questions

In order to ensure that all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of the Small Biotech Exception, the Submitting Manufacturer must provide its employer identification number(s) (EIN(s)), and the EIN(s) of any members of its controlled group that had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021. Or, if the qualifying single source drug for which it is seeking the exception was acquired after December 31, 2021, the Submitting Manufacturer must provide the EIN(s) of the entity that had a Medicare Coverage Gap Discount Program agreement for the qualifying single source drug on December 31, 2021, and the EIN(s) of any members of that entity's controlled group that had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021.

12. Burden Estimates (Hours & Wages)

A Submitting Manufacturer must complete and submit the information requested on this form in order for the drug to be considered for the Small Biotech Exception for initial price applicability year 2026. If the Submitting Manufacturer seeks the Small Biotech Exception for a qualifying single source drug it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021.

To identify wage estimates, we used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with completing the Small Biotech Exception Information Collection Request Form, form submission, and recordkeeping.[5] Tables 1 and 2 present the mean hourly wage, the cost of fringe benefits and overhead, the adjusted hourly wage, along with total burden and total cost.

We estimate 10 total respondents in 2023. We believe that collection of these data will be a one-time cost for each Submitting Manufacturer for each qualifying single source drug for which it is seeking the Small Biotech Exception for initial price applicability year 2026.

[5] See May 2021 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/oes_stru.htm.

We estimate that nine Submitting Manufacturers will not have acquired their drug after December 31, 2021, and will therefore provide information only about their own entity. We estimate it will take a lawyer, on average, five hours, at a cost per hour of $142.34, to gather and review the relevant Internal Revenue Code provisions and to identify any controlled group members that as of December 31, 2021 were treated as a single employer with the Submitting Manufacturer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 and had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021, and therefore must be counted together by CMS when calculating 2021 Medicare expenditures for all covered Part D drugs for which the entity has an agreement under the Medicare Coverage Gap Discount Program. We estimate that it will take a general operations manager, on average, two hours, at $110.82 per hour, to examine the gathered information and submit the Small Biotech Exception Information Collection Request Form to CMS. We estimate that it will take a chief executive, on average, 15 minutes, or 0.25 hours, at $204.82 per hour, to review the information prior to submission and to log in to CMS' existing information technology system to certify the submission. Certification must be done by (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).

We have presented the cost estimates in Table 1. We estimate a total burden of 56.25 hours (6.25 hrs.* 9 respondents) and total cost $7,863.53 ($873.73 per respondent * 9 respondents).

TABLE 1: SUMMARY OF INFORMATION COLLECTION FOR DRUGS NOT ACQUIRED AFTER DECEMBER 31, 2021, FOR THE ONE TIME COST OVER THE ONE-YEAR PERIOD

Occupation Title	Mean Hourly Wage	Cost per hour	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Lawyer (23-1011)	$71.17	$142.34	5	9	45	$6,405.30
General Operations Manager (11-1021)	$55.41	$110.82	1	9	9	$997.38
Chief Executive (11-1011)	$102.41	$204.82	0.25	9	2.25	$460.85
Total		-	6.25	9	56.25	$7,863.53
Cost per Respondent						$873.73

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies.

We estimate that one Submitting Manufacturer will have acquired the drug since December 31, 2021, and will have to obtain the relevant information from the entity that had the Coverage Gap

Discount Program agreement for the qualifying single source drug as of December 31, 2021. We estimate it will take a lawyer, on average, 10 hours, at a cost per hour of $142.34, to gather and review the relevant Internal Revenue Code provisions, including contacting the entity that had the Coverage Gap Discount Program agreement for the qualifying single source drug in 2021 to identify any controlled group members that as of December 31, 2021 were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 and had a Medicare Coverage Gap Discount Program agreement in effect on December 31, 2021, and therefore must be counted together by CMS when calculating 2021 Medicare expenditures for all covered Part D drugs for which that entity had an agreement under the Medicare Coverage Gap Discount Program. We estimate that it will take a general operations manager, on average, two hours, at $110.82 per hour, to examine the gathered information and submit the Small Biotech Exception Information Collection Request Form to CMS. We estimate that it will take a chief executive, on average, 15 minutes, or 0.25 hours, at $204.82 per hour, to review the information prior to submission and to log in to CMS' existing information technology system to certify the submission. Certification must be done by (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).

We have presented the cost estimates in Table 2. We estimate a total burden of 12.25 hours (12.25 hrs.* 1 respondent) and total cost $1,696.25 ($1,696.25 per respondent * 1 respondent).

TABLE 2: SUMMARY OF INFORMATION COLLECTION FOR DRUGS ACQUIRED AFTER DECEMBER 31, 2021, FOR THE ONE TIME COST OVER THE ONE-YEAR PERIOD

Occupation Title	Mean Hourly Wage	Cost per hour	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Lawyer (23-1011)	$71.17	$142.34	10	1	10	$1,423.40
General Operations Manager (11-1021)	$55.41	$110.82	2	1	2	$221.64
Chief Executive (11-1011)	$102.41	$204.82	0.25	1	.25	$51.21
Total		-	12.25	1	12.25	$1,696.25
Cost per Respondent						$1,696.25

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies.

For all 10 respondents, we estimate a total burden of 68.5 hours and total cost of $9,559.77.

13. Capital Costs

There are no anticipated capital costs associated with this information collection.

14. Cost to Federal Government

To generate salary estimates for the table below, we used: the 2022 General Schedule (GS) Locality Pay Tables[6] published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region. In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. Staffing estimates are based on CMS duties as follows:

We anticipate that one GS-13 Federal employee will spend approximately 40 hours, or one FTE approximately one week, maintaining the Small Biotech Exception Information Collection Request Form and analyzing data collected through the Form. The adjusted hourly wage of $102.36 is the total of the hourly rate of $51.18 for one GS-13 step-1 plus 100 percent fringe benefit rate of $51.18. We anticipate that one GS-13 Federal employee will spend approximately 16 hours handling communications with Submitting Manufacturers, including notifying each Submitting Manufacturer of CMS' determination regarding its Small Biotech Exception request and providing technical assistance with the HPMS tool. We anticipate that other GS-13 Federal employees will spend a total of 200 hours, or the equivalent of one FTE approximately five weeks, to provide technical direction to a contractor that will develop an automated tool within an existing information technology system for the Submitting Manufacturers to submit the Small Biotech Exception Information Collection Request Form. We anticipate that this contractor will spend a total of 1,120 hours at a cost of $245.54 per hour.

TABLE 3. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT DETERMINATION OF SINGLE EMPLOYER STATUS OF PHARMACEUTICAL DRUG MANUFACTURERS

Task	Estimated Cost
Small Biotech Exception Review GS-13 (step 1): (1 x $102.36 x 40 hours)	$4,094.40
Communicating with Submitting Manufacturers GS-13 (step 1): (1 x $102.36 * 16 hours)	$1,637.76
Modification of existing system GS-13 (step 1): (1 x $102.36 x 200 hours) Contractor: 1 x $245.54 x 1,120 hours)	$295,476.80
Total Cost to Government Over 1 Years	$301,208.96

15. Changes to Burden

[6] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB_h.pdf

This is a new information collection request; however, the following change was made in response to multiple comments received in response to the 60-day notice (88 FR 4184). CMS adjusted the burden estimate of total cost for the federal government to reflect time spent communicating with Submitting Manufacturers, including providing technical assistance with the HPMS tool.

16. Publication/Tabulation Dates

The results of this information collection will not be published.

17. Expiration Date

The expiration date and OMB control number will be displayed within the data collection information technology system.

18. Certification Statement

There are no exceptions to the certification statement.