Supporting Statement – Part A

Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR)

(CMS-10849, OMB 0938-1452)

Introduction

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 ("the Negotiation Program"), codified in sections 1191 through 1198 of the Social Security Act ("the Act"). The purpose of this collection of information request is for CMS to collect information to implement the Medicare Drug Price Negotiation Program in accordance with the proposed policies in the Medicare Drug Price Negotiation Program rule ("proposed rule") (CMS-4215-P, RIN 0938-AV90).

The Act establishes the Negotiation Program to negotiate a maximum fair price ("MFP"), defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs covered under Medicare Part B and Part D ("selected drugs").[1] For initial price applicability year 2029 and initial price applicability years thereafter, CMS will select for negotiation up to 20 high expenditure, single source drugs payable under Part B and/or covered under Part D. Any MFPs that are negotiated for these drugs will apply beginning in the initial price applicability year for such negotiated MFP. The negotiation period for an initial price applicability year begins February 28 of the calendar year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation, or the date that the manufacturer of a selected drug enters into a Medicare Drug Price Negotiation Program Agreement (an "Agreement") with CMS, whichever is sooner. For initial price applicability year 2028 and initial price applicability years thereafter, CMS will also renegotiate MFPs for drugs selected for renegotiation (if any), in accordance with section 1194(f)(4) of the Act. For renegotiated drugs, Primary Manufacturers are obligated to make the renegotiated MFP available when the drug is dispensed, furnished, or administered to MFP-eligible individuals on or after January 1 of the initial price applicability year for which the drug was selected for renegotiation.

For the purposes of this ICR, a selected drug for an initial price applicability year is defined as a drug included on the selected drug list published by CMS not later than the selected drug publication date for an initial price applicability year as defined in proposed 42 CFR 429.20.

---

1 For the purposes of this ICR, qualifying single source drug has the same definition as it is given proposed 42 CFR 429.20.

CMS will also publish the selected drugs selected for renegotiation for an initial price applicability year following the same timeframe as the newly selected drugs. A Primary Manufacturer that has an Agreement in effect, as discussed in proposed 42 CFR 429.200, will be

required to adhere to the process and deadlines described in proposed 42 CFR Part 429, including proposed 42 CFR 429.200(a). In section 1191(c)(1) of the Act, the statute adopts the definition of a manufacturer established in section 1847A(c)(6)(A) of the Act, proposed in 42 CFR §429.20. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. In accordance with proposed 42 CFR 429.20, to the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2029, CMS will designate the entity that holds the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer"). Likewise, in accordance with proposed 42 CFR 429.20, for an initial price applicability year, CMS will refer to any manufacturer of a drug product included in the selected drug, and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer as a "Secondary Manufacturer."

This ICR addresses three components of the Negotiation Program. First, CMS considers two sets of factors as the basis for determining offer(s) and counteroffer(s) throughout the negotiation and renegotiation process in accordance with sections 1194(e) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.505 and 429.620(c): (1) certain data that must be submitted by the manufacturer of each drug selected as described in section 1194(e)(1); and (2) evidence, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug as described in section 1194(e)(2) collectively, (the "Negotiation Data Elements" (NDE)). Second, in accordance with section 1194(d) of the Act, CMS will collect the information necessary for CMS to determine whether, at the request of the manufacturer of a selected drug, in initial price applicability year 2029 or initial price applicability year 2030 such drug qualifies for the temporary floor for small biotech drugs (the "Temporary Floor for Small Biotech Drugs"). Third, in accordance with section 1194(b)(2)(C) of the Act, a manufacturer may submit an optional written counteroffer (referred to herein as the "statutory written counteroffer"), including an Addendum populated with the counteroffer proposal for the MFP as described in proposed 42 CFR 429.525, if CMS' written initial offer is not accepted by the Primary Manufacturer. In accordance with section 1194(f)(4)(B) of the Act and to conform to the procedures, structure, and timing of the negotiation process as described in proposed 42 CFR 429.620(g), a manufacturer may submit an optional written counteroffer (referred to herein as the "renegotiation written counteroffer") if CMS' written initial offer is not accepted by the Primary Manufacturer during the renegotiation process.[2]

If information within a section of this Supporting Statement applies to only the Negotiation Data Elements, the Temporary Floor for Small Biotech Drugs, or the Counteroffer, a subtitle heading

2 The statutory written counteroffer and renegotiation written counteroffer are hereinafter collectively referred to as the "Counteroffer."

corresponding to the name of the applicable collection form will be listed before the applicable information.

Within the information collection request for the Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (CMS-10844, OMB 0939-1443)[3], CMS previously included the information collection for a manufacturer to request a Small Biotech Exception, which, in accordance with section 1192(d)(2) of the Act, provided for the exclusion of an otherwise "negotiation-eligible drug" with respect to initial price applicability years 2026, 2027, and 2028, for a qualifying single source drug that met the requirements for the exception for small biotech drugs (the "Small Biotech Exception" or "SBE"). Since the statutory provision providing for a SBE does not apply to initial price applicability year 2029 and beyond but the eligibility for the Temporary Floor for Small Biotech Drugs is based on the statutory requirements to qualify as a "small biotech drug" for an SBE, CMS has removed the Small Biotech Exception Form from the Drug Selection ICR and CMS includes revisions in this Drug Price Negotiation ICR to collect information necessary for CMS to determine eligibility of selected drugs for the Temporary Floor for Small Biotech Drugs.

CMS intends to annually incorporate technical revisions in this ICR for references to a calendar year or other specific date. For example, these technical revisions would include references to initial price applicability year 2029 and calendar year 2027 for the first year of this revised ICR. CMS would continue to provide any proposed substantive revisions and requests for renewal of the package for public comment consistent with the Paperwork Reduction Act.

If a term included in this ICR Form is also included and defined in proposed 42 CFR § 429.20 or § 429.440, the term's definition in this form is the same as in the proposed rule. Definitions otherwise included in this form are intended for purposes related to this form and the Medicare Drug Price Negotiation Program only. CMS will incorporate revisions included with the final rule that are also applicable to this ICR via the final version of this ICR.

A. Background

Negotiation Data Elements ICR Form

In accordance with section 1193(a)(4) and section 1194(b)(2)(A) of the Act, the manufacturer must submit, in a form and manner specified by CMS, information on the non-Federal average manufacturer price ("non-FAMP") as defined in 38 U.S.C. 8126(h)(5) for the selected drug and information that CMS requires to carry out the negotiation process, including the factors outlined in section 1194(e)(1) of the Act, which, in conjunction with the available evidence on the factors outlined in section 1194(e)(2), will serve as the basis for determining the initial offer, any

3 Available on the Office of Management and Budget's website at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202509-0938-014.

offer(s) associated with negotiation meeting(s), and the final offer, if applicable. In addition, manufacturers and the public may submit information on the factors outlined in section 1194(e)(2) of the Act, which describes evidence about the selected drug and its therapeutic alternative(s). In accordance with section 1194(f)(4)(B) of the Act and proposed 42 CFR 429.603(b), CMS will apply a similar approach regarding data collection once a drug is selected for renegotiation of the MFP, if any drugs are selected for renegotiation.

In accordance with proposed 42 CFR 429.100(d), 429.505 and 429.615(b), CMS will collect certain data from the Primary Manufacturer, including information on non-FAMP and the data identified in section 1194(e)(1) of the Act, and will collect information on evidence about a selected drug and its therapeutic alternatives per section 1194(e)(2) of the Act from any interested party. This ICR Form serves as one of multiple ways that CMS will collect data described in section 1194(e)(2) of the Act.

Temporary Floor for Small Biotech Drugs ICR Form

In accordance with section 1194(d) of the Act and proposed 42 CFR 429.440, the Primary Manufacturer of a selected drug may submit a request with respect to initial price applicability year 2029 and 2030 for CMS' consideration to be determined eligible for the Temporary Floor for Small Biotech Drugs.

For initial price applicability year 2029 and initial price applicability year 2030, section 1194(d) of the Act, pursuant to section 1192(d) of the Act, requires CMS to evaluate whether a selected drug meets the requirements as a "small biotech" drug based on Total Expenditures under Part D or Part B, as proposed in 42 CFR 429.120, if the drug is selected for negotiation or renegotiation with respect to initial price applicability year 2029 or 2030. CMS will make separate determinations with respect to the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track"), and the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"). With respect to a drug selected for negotiation for initial price applicability year 2029 and 2030, or a drug selected for renegotiation for initial price applicability year 2029 or 2030, for which the Primary Manufacturer submits information in accordance with proposed 42 CFR 429.440(b)(1), and is eligible for the Temporary Floor for Small Biotech Drugs, CMS will not offer or accept an MFP that is below the Temporary Floor for Small Biotech Drugs. The Temporary Floor for Small Biotech Drugs will be established at 66 percent of the average non-FAMP price for such drug for 2021, increased by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U) from September 2021 to September of the year prior to the selected drug publication date with respect to the initial price applicability year. If a selected drug does not have an average non-FAMP for 2021, the average non-FAMP for the first full year following the market entry for the selected drug will be used, increased by the percentage increase in the CPI-U from December of the first full year following the market entry to September of the year prior to the selected drug publication date (defined in proposed 42 CFR 429.20).

For the purposes of the Temporary Floor for Small Biotech Drugs and proposed 42 CFR 429.440, CMS needs to collect information to accurately identify: the "Part D 2021

Manufacturer," which is the entity that either had a Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A of the Act in effect for the qualifying single source drug on December 31, 2021 or had an arrangement whereby the manufacturer's labeler codes were listed on another manufacturer's Medicare CGDP Agreement, consistent with section 1860D-14A of the Act, in effect on December 31, 2021; and/or the "Part B 2021 Manufacturer," which is the New Drug Application (NDA) holder or the Biologics License Application (BLA) holder for the qualifying single source drug on December 31, 2021. In addition, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all corporations or partnerships, sole proprietorships, and other entities that, on December 31, 2021, were treated as a single employer (i.e., part of the same controlled group) under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 (IRC) with the Part D 2021 Manufacturer or Part B 2021 Manufacturer. The Part D 2021 Manufacturer and its controlled group, as defined in proposed 42 CFR 429.440(a), comprises all persons 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 with the Part D 2021 Manufacturer. To accurately identify whether a selected drug meets the criteria in accordance with section 1192(d)(2)(A)(i) of the Act, CMS collects the name, address, Employer Identification Number (EIN), unique identifier assigned by CMS (P Number), and labeler code(s) owned by the Part D 2021 Manufacturer and the entity(ies) in the Part D 2021 Manufacturer's controlled group. The Part B 2021 Manufacturer and its controlled group, as defined in proposed 42 CFR 429.440(a), comprises all persons 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 with the Part B 2021 Manufacturer. To accurately identify whether a selected drug meets the criteria in accordance with section 1192(d)(2)(A)(ii) of the Act, CMS collects the name, address, EIN, and unique identifier assigned by CMS (P Number) for the Part B 2021 Manufacturer and the entity(ies) in the Part B 2021 Manufacturer's controlled group. CMS also collects the NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer and the entity(ies) in the Part B 2021 Manufacturer's controlled group.

In applying the Part D Track, the statute requires that CMS consider Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures under Part D for the selected drug during 2021, and Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021.[4] To identify the selected drug(s) eligible for the Temporary Floor for Small Biotech Drugs, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures during 2021 under Part D for the selected drug were: (1) equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs during

4 As stated in section 50.1.1 of the Revised Medicare Part D Manufacturer Discount Program Final Guidance, dated December 20, 2024, available at https://www.cms.gov/files/document/manufacturer-discount-program-finalguidance.pdf (hereinafter, the "Manufacturer Discount Program Final Guidance"): "A manufacturer that participated in the CGDP in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's
CGDP Agreement would be considered to have had an agreement in effect during 2021."

2021; and (2) equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021. [5]

In applying the Part B Track, the statute requires that CMS consider Total Expenditures under Part B in 2021 for all qualifying single source drugs, Total Expenditures under Part B during 2021 for the selected drug, and Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group. To identify the selected drug(s) eligible for the Temporary Floor for Small Biotech Drugs, CMS will consider whether, for Original Medicare (OM) Part B claims data and Medicare Advantage (MA) encounter data for Part B items and services (hereinafter collectively referred to as "Part B data") with dates of service in calendar year 2021, the Total Expenditures under Part B as determined using Part B data during 2021 for the selected drug were: (1) equal to or less than one percent of the Total Expenditures under Part B for all qualifying single source drugs paid under Part B during 2021; and (2) equal to at least 80 percent of the Total Expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group for which payment may be made under Part B.

Additionally, the limitation at section 1192(d)(2)(B)(ii) of the Act would preclude a selected drug from qualifying as a "small biotech" drug consistent with section 1192(d) of the Act if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) effective at the beginning of the plan year immediately following such acquisition (which is, in the case of an acquisition before 2025, effective January 1, 2025, or in the case of an acquisition for 2025 and after, for January 1 of the plan year immediately following the acquisition).[6] For purposes of implementing this limitation, CMS will use the determination made under the Medicare Part D Manufacturer Discount Program (the "Manufacturer Discount Program") as to whether the acquiring entity met the definition of specified manufacturer in the applicable period. CMS will consider an acquiring entity to have met the Manufacturer Discount Program definition of specified manufacturer for purposes of this limitation if the acquiring entity is identified by CMS under the Manufacturer Discount Program as either a specified manufacturer under section 1860D-14C(g)(4)(B)(ii) or a specified small manufacturer under section 1860D14C(g)(4)(C)(ii) of the Act. For an acquisition of a manufacturer to be relevant to the limitation, and therefore to potentially preclude a drug from being considered a selected drug that could be eligible for the Temporary Floor for Small Biotech Drugs, the transaction must occur after 2021 and must

5 Consistent with proposed 42 CFR 429.20 and 429.125, for purposes of identifying the qualifying single source drugs that comprise the ratios described in 1192(d)(2)(A), CMS will identify drugs that meet the definition of a qualifying single source drug for initial price applicability year 2029 based on the aggregation policies set forth in proposed 42 CFR 429.125.

6 *See* section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, dated December 20, 2024, available at https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf, and, *see also*, the November 17, 2023 HPMS memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers", available at https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-smallmanufacturermethodology.pdf, for more information.

involve the acquisition of the Primary Manufacturer after the Primary Manufacturer held the NDA(s) / BLA(s) for the selected drug. A determination by CMS that a given selected drug is eligible for the Temporary Floor for Small Biotech Drugs for an initial price applicability year is not based on whether or not CMS previously determined that a selected drug was eligible or not eligible for the Small Biotech Exception in initial price applicability years 2026, 2027, and/or 2028.

Counteroffer ICR Form

CMS intends to implement the offer and counteroffer process with the goal of negotiating to achieve agreement on "the lowest [MFP] for each selected drug" consistent with section 1194(b)(1) of the Act. In accordance with sections 1194(b)(2)(B) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.520(a) and 429.620(f), CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug or the proposal of a renegotiated MFP for a selected drug for initial price applicability year 20XX no later than June 1 of the calendar year of the selected drug publication date for the initial price applicability year that the drug is selected for negotiation or renegotiation. In accordance with sections 1194(b)(2)(C) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.525(a) and 429.620(g), the Primary Manufacturer will respond to CMS' written initial offer no later than 30 days after the date of receipt of the written initial offer from CMS. If the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer will submit the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable, including an Addendum to the Negotiation Program Agreement populated with the proposal for the MFP.[7] In accordance with sections 1194(b)(2)(D) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.525(c) and 429.620(g), CMS will provide a written response to the statutory written counteroffer and the renegotiation written counteroffer, respectively. CMS will provide this response within 30 days of receipt or within 60 days of sharing the written initial offer, whichever is later. If CMS rejects the Primary Manufacturer's Counteroffer, CMS and Primary Manufacturers can choose to initiate additional, written offers and counteroffers via the additional price exchange module in the CMS HPMS. More information on the negotiation process can be found in 42 CFR subpart F and more information on the renegotiation process can be found in proposed 42 CFR subpart G.

Every written offer and counteroffer, including a Counteroffer, will include an Addendum to the Negotiation Program Agreement populated with the proposal for the MFP. If an agreement on the MFP is reached at any point during the negotiation process described at 42 CFR subpart F or the renegotiation process described at 42 CFR subpart G, the Addendum to the Negotiation Program Agreement, as described in proposed 42 CFR 429.200(e), will be executed by both parties and will constitute agreement on the MFP.[8] The MFP included in the executed

Addendum to the Negotiation Program Agreement will apply for the selected drug for that first initial or renegotiated initial price applicability year and will be updated according to section

7 The Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form are collectively referred to as the "Counteroffer ICR Form."

8 To the extent applicable, any references in the proposed rule to the "MFP" includes a renegotiated MFP.

1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable. Refer to proposed 42 CFR 429.620(k) and 429.705 and for information on how the MFP will be updated for subsequent years in the price applicability period.

CMS is requesting approval of revisions to this ICR package based on lessons learned from implementation of the Negotiation Program to improve clarity of instructions to ensure high quality and consistent data across submissions, to improve CMS' ability to conduct compliance reviews of such submissions, and to continue implementation of the IRA. Additionally, CMS incorporates policy revisions, as applicable, to reflect parallel changes made to the proposed rule. CMS believes that the changes will contribute to a more efficient preparation process for respondents in preparing to answer the Drug Price Negotiation ICR.

B. Justification

1. Need and Legal Basis

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

In accordance with sections 1194(e) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.505 and 429.615(b), CMS will consider certain factors, as applicable to the selected drug, as the basis for determining its offers. As described in proposed 42 CFR 429.505 and 429.615(b), these factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. A Primary Manufacturer that has an Agreement in effect, as discussed in proposed 42 CFR 429.200, will be required to adhere to the process and deadlines for negotiation and renegotiation, including related to data submission, described proposed 42 CFR 429.505 and 429.615(b).

These data include the following and are required to be reported by the Primary Manufacturer to CMS by March 1 of the year of the selected drug publication date for the initial price applicability year that the drug is selected for negotiation or renegotiation:

1. Research and development (R&D) costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs;
2. Current unit costs of production and distribution of the selected drug, averaged across the Primary Manufacturer and any Secondary Manufacturer(s);
3. Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;
4. Data on pending and approved patent applications, exclusivities recognized by the U.S. Food and Drug Administration (FDA), and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or section 351(a) of the Public Health Service Act (PHS Act) for the selected drug; and

5. Market data and revenue and sales volume data for the selected drug in the United States for the Primary Manufacturer and any Secondary Manufacturer(s).

Pursuant to proposed 42 CFR 429.100(d), 429.405(a), 429.505(a), and 429.615(b), the Primary Manufacturer should submit information in the CMS Health Plan Management System (the "CMS HPMS") for each 11-digit National Drug Code (NDC-11) of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to proposed 42 CFR 429.100(c). As noted above, CMS requires the Primary Manufacturer to aggregate data from both the Primary Manufacturer and any Secondary Manufacturer(s) for the following: non-FAMP, current unit costs of production and distribution, and certain data pertaining to market data and revenue and sales volume data for the selected drug.

Additionally, as specified in proposed 42 CFR 429.100(e), 429.405(b) and 429.505(b), the Primary Manufacturer has an ongoing obligation to timely report certain updates to data submissions required of Primary Manufacturers under sections 1193(a)(4)(A) and 1194(e)(1) of the Act and previously submitted to CMS through the initial response to the Negotiation Data Elements ICR Form.

Evidence About Alternative Treatments

In accordance with sections 1194(e)(2) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.505(c) and 429.615(b), CMS will consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, as described in proposed 42 CFR 429.505(c) and 429.615(b), CMS will allow for optional submissions once a drug is selected for negotiation or renegotiation from Primary Manufacturers and the public, including Secondary Manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, patients or patient organizations, and other interested parties. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in section 1194(e)(2) to ensure consideration of such factors. Primary Manufacturers may submit this information as part of their Negotiation Data Elements ICR Form. The public may optionally submit evidence about selected drugs and their alternative treatments.

Section 1194(e)(2) lists additional factors that CMS will consider, as available:

- The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
- Prescribing information in the FDA-approved labeling for the selected drug and for its therapeutic alternatives;
- Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations); and

- The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

The Negotiation Data Elements ICR Form for manufacturer-submitted data elements and public submissions about evidence about alternative treatments must be submitted to CMS not later than March 1 of the year of the selected drug publication date for the initial price applicability year that the drug is selected for negotiation or renegotiation (consistent with 42 CFR 429.20, 429.100(d), 429.405(a), 429.505, and 429.615(b)).

Temporary Floor for Small Biotech Drugs ICR Form

CMS currently does not have information to determine whether manufacturers of drugs and biological products payable under Part B and/or covered under Part D were treated as a single employer with other entities under subsection (a) or (b) of section 52 of the IRC as of December 31, 2021. This information is required in order for CMS to accurately identify whether a given drug qualifies as a "small biotech" drug, consistent with section 1192(d)(2) of the Act, for purposes of determining if the drug is eligible for the Temporary Floor for Small Biotech Drugs in accordance with section 1194(d) of the Act. For the Part D Track, to ensure that only selected drugs that meet the requirements are eligible for the Temporary Floor for Small Biotech Drugs, a Primary Manufacturer must submit to CMS information for the Part D 2021 Manufacturer and the Part D 2021 Manufacturer and its controlled group such as the Employer Identification Number(s) (EIN(s)), P number(s), labeler code(s) owned by each entity that are associated with the entity's unique identifier (P number), and labeler code(s) owned by each entity that are associated with unique identifier(s) (P number(s)) owned by other entities. For the Part B Track, to ensure that only selected drugs that meet the requirements are eligible for the Temporary Floor for Small Biotech Drugs, a Primary Manufacturer must submit to CMS the EIN(s) and NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer and the Part B 2021 Manufacturer and its controlled group on December 31, 2021.

Finally, to implement the limitation at section 1192(d)(2)(B)(ii) of the Act, CMS needs information from the Primary Manufacturer to assess whether the Primary Manufacturer was the subject of an acquisition which would render the Primary Manufacturer's selected drug ineligible for the Temporary Floor for Small Biotech Drugs.

The Temporary Floor for Small Biotech Drugs ICR Form may be submitted to CMS no later than March 1, 2027, for initial price applicability year 2029.

Primary Manufacturers who might benefit from submitting the Temporary Floor for Small Biotech Drugs ICR Form for initial price applicability year 2029 are those manufacturers of a selected drug who believe that the selected drug meets the criteria for the Temporary Floor for Small Biotech Drugs as set forth in section 1194(d) of the Act and proposed 42 CFR 429.440.

Counteroffer ICR Form

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional statutory written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer. If the Primary Manufacturer chooses to develop and submit such statutory written counteroffer to CMS' written initial offer during the negotiation process for the initial price applicability year, the Primary Manufacturer must submit the Statutory Written Counteroffer ICR Form. Section 1194(f)(4)(B) of the Act provides that CMS shall, to the extent practicable, establish a renegotiation process that is consistent with the methodology and process established for negotiation under section 1194(b) of the Act, and in accordance with sections 1194(c), (d), and (e) of the Act. Consistent with the negotiation process described in proposed 42 CFR 429.525, if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional renegotiation written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer in accordance with proposed 42 CFR 429.620(g). If the Primary Manufacturer chooses to develop and submit such renegotiation written counteroffer to CMS' written initial offer during the renegotiation process for the initial price applicability year, the Primary Manufacturer must submit the Renegotiation Written Counteroffer ICR Form.

2. Information Users

Under the authority of sections 1193 and 1194 of the Act, CMS is authorized to collect data and information required for negotiation and renegotiation. CMS will use the submitted information to negotiate or renegotiate, as applicable, and seek to reach agreement on an MFP, as applicable, for the selected drug with the Primary Manufacturer.

3. Use of Information Technology

Negotiation Data Elements ICR Form

<u>Manufacturer-Specific Data</u>

CMS has developed an automated tool within an existing information technology system used by manufacturers of drugs covered under Medicare Part D, the CMS HPMS, for Primary Manufacturers to provide the Negotiation Data Elements using the ICR form. Manufacturers of drugs payable under Medicare Part B use the CMS HPMS for the Medicare Prescription Drug Inflation Rebate Program. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (CMS HPMS) for the Medicare Drug Price Negotiation Program" PDF. Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

The individuals who certify the Primary Manufacturer's data elements submission in the CMS HPMS must be: (1) the chief executive officer (CEO) of the Primary Manufacturer, (2) the chief financial officer (CFO) of the Primary Manufacturer, (3) an individual with equivalent authority

to a CEO or a CFO of the Primary Manufacturer, or (4) an individual that has been granted delegation of signature authority on behalf of one of the individuals mentioned in (1) through (3).

Evidence About Alternative Treatments

Pursuant to proposed 42 CFR 429.505 and 429.620(b), the Primary Manufacturer of a selected drug may optionally submit any evidence about their selected drugs and their alternative treatments as part of their larger data submission in the CMS HPMS.

In accordance with proposed 42 CFR 429.505(c) and 429.615(a), members of the public may optionally submit evidence about alternative treatments via a publicly available web link that will be posted in the Medicare Drug Price Negotiation Program section of CMS.gov (https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicaredrug-price-negotiation-program) and the CMS HPMS landing page (https://hpms.cms.gov). Additional instructions to access this public web application will be forthcoming from CMS and made available on CMS.gov via the Medicare Drug Price Negotiation Program section.

Temporary Floor for Small Biotech Drugs ICR Form

Pursuant to proposed 42 CFR 429.440, the Primary Manufacturer of a selected drug may optionally submit information so that CMS can make a determination of whether the selected drug is eligible for the Temporary Floor for Small Biotech Drugs. CMS has developed an automated tool within the CMS HPMS for Primary Manufacturers to submit the Temporary Floor for Small Biotech Drugs ICR Form. Instructions for Primary Manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS HPMS for the Medicare Drug Price Negotiation Program" PDF.[9] Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

The individuals who certify the Primary Manufacturer's submission in the CMS HPMS must be: (1) the CEO of the Primary Manufacturer, (2) the CFO of the Primary Manufacturer, (3) an individual with equivalent authority to a CEO or a CFO of the Primary Manufacturer, or (4) an individual that has been granted delegation of signature authority on behalf of one of the individuals mentioned in (1) through (3).

Counteroffer ICR Form

CMS has developed an automated tool within the CMS HPMS for Primary Manufacturers to submit the Counteroffer using the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable. Instructions for manufacturers to gain access to the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in

9 https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-planmanagement-system-cms-hpms-medicare.pdf.

the CMS HPMS for the Medicare Drug Price Negotiation Program" PDF. [10] Instructions for gaining signatory access to the CMS HPMS are also included in this PDF.

The individuals who certify the Primary Manufacturer's Counteroffer submission in the CMS HPMS must be: (1) the CEO of the Primary Manufacturer, (2) the CFO of the Primary Manufacturer, (3) an individual with equivalent authority to a CEO or a CFO of the Primary

Manufacturer, or (4) an individual that has been granted delegation of signature authority on behalf of one of the individuals mentioned in (1) through (3).

4. Duplication of Efforts

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

Some manufacturer-specific data described in sections 1193(a)(4) and 1194(e)(1) of the Act and proposed 42 CFR 429.100(d), 429.405(a), 429.505(a), and 429.615(b) may already be collected from manufacturers by CMS or other federal agencies. For example, drug manufacturers currently submit data related to manufacturer financials, such as total net revenue (e.g., 10-K filings with the Securities and Exchange Commission). Additionally, in accordance with the terms of the National Drug Rebate Agreement and section 1927(b)(3)(A) of the Act, drug manufacturers participating in the Medicaid Drug Rebate Program (MDRP) are required to report Average Manufacturer Price (AMP) to CMS each quarter for their covered outpatient drugs. For purposes of calculating the federal ceiling price, drug manufacturers also report the quarterly and annual non-FAMP on an annual basis to the Department of Veterans Affairs (VA). The Federal Supply Schedule[11] and the Big Four[12] are prices negotiated by the VA and are available publicly. In addition, some of the requested data may be publicly available, although CMS may not be able to ensure that such data are complete or up-to-date. Data that are publicly available may not match the ICR specifications, including time periods required for the Negotiation Program. CMS believes that the Primary Manufacturer is best positioned to provide the requested data and the statute and the proposed rule provide that manufacturers participating in the Negotiation Program will submit the requested data.

---

10 https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-planmanagement-system-cms-hpms-medicare.pdf.

11 The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule/aboutgsaschedule#:~:text=The%20GSA%20Schedule%2C%20also%20known,reasonable%20prices%20to%20the%20go vernment.

12 The Big Four price is the maximum price a drug manufacturer is allowed to charge the "Big Four" federal agencies, which are the VA, Department of Defense (DoD), the Public Health Service, and the Coast Guard. See generally 38 U.S.C. 8126; https://www.cbo.gov/publication/57007.

Evidence About Alternative Treatments

In accordance with sections 1194(e)(2) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.505(c) and 429.615(b), CMS will consider certain data on selected drugs and their alternative treatments. Pursuant to proposed 42 CFR 429.505(c) and 429.615(b), this information may be obtained through multiple sources, such as academic studies and papers, extant systematic reviews of evidence, government and other reports, and clinical guidelines, and is optional for the Primary Manufacturer and public to submit. CMS intends to consider clinical evidence available through academic studies and papers, extant systematic reviews of evidence, government and other reports, subject matter experts, clinical experts (e.g., Medicare beneficiaries, academic experts, clinicians, caregivers, patients or patient organizations, and other interested parties), and data analyses.

Temporary Floor for Small Biotech Drugs ICR Form

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

Counteroffer ICR Form

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 toward minimizing the reporting burden for Primary Manufacturers, which are the only entities required to submit manufacturer specific data and evidence about selected drugs. Drugs with the highest total expenditures payable under Medicare Part B and/or covered under Medicare Part D will be selected for negotiation for an initial price applicability year. Drugs selected for renegotiation, if any, were initially selected for negotiation because they were drugs with the highest expenditures payable under Part B and/or covered under Medicare Part D. While Primary Manufacturers that are eligible for the Temporary Floor for Small Biotech Drugs may be considered small businesses, the impacts of this collection on a Primary Manufacturer seeking to qualify for the Temporary Floor for Small Biotech Drugs are estimated to be the same regardless of the size of the Primary Manufacturer.

Moreover, the Counteroffer ICR Form is required only if Primary Manufacturers of selected drugs choose to make a Counteroffer submission to the agency's proposed MFP for the selected drug in the written initial offer, and Primary Manufacturers are the only entities authorized by statute to submit this information. Where a manufacturer is subject to the information collection, the impact of this collection on a Primary Manufacturer is estimated to be the same regardless of the size of the Primary Manufacturer.

6. Less Frequent Collection

Negotiation Data Elements ICR Form

Manufacturer-Specific Data

Forgoing collection of this information or collecting the information less frequently are not options because Primary Manufacturers are required to submit non-FAMP data and information required to carry out negotiation and renegotiation per sections 1193(a)(4) and 1194(f)(4)(B) of the Act. Without these data, CMS would not be able to conduct negotiations and renegotiations as directed by the IRA.

Evidence About Alternative Treatments

Submission of information about selected drugs and their alternative treatments will be voluntary for both manufacturers and the public. Should CMS forgo this information request, manufacturers and the public would not be able to provide input on negotiation factors that the agency is required to consider when carrying out negotiation and renegotiation. CMS believes that additional information from patients and consumers, Part D plan sponsors and Medicare Advantage organizations, Primary and Secondary Manufacturers of selected drugs, manufacturers of therapeutic alternatives for a selected drug, hospitals and health care providers, wholesalers, pharmacies, researchers, and other members of the public may provide additional insight into selected drugs and their alternative treatments. By making this portion of the information request voluntary, CMS seeks to alleviate unnecessary burden while still providing interested parties with the opportunity to comment. CMS has continued to consider design alternatives for Section I with each annual cycle to both simplify the steps for respondents to access the submission webpage and options for submission of responses to the form that reduce respondent burden.

Temporary Floor for Small Biotech Drugs ICR Form

Less frequent collection would not be an option because the Primary Manufacturer may choose to submit the information only once per selected drug and for the initial price applicability year for which the Primary Manufacturer seeks to be eligible for the Temporary Floor for Small Biotech Drugs.

Counteroffer ICR Form

Less frequent collection would not be an option because the statute contemplates a Primary Manufacturer would submit the information only once, if applicable, in response to the initial offer from CMS for each selected drug for which the Primary Manufacturer chooses to engage in negotiation with CMS for the initial price applicability year for which the drug is selected for negotiation. In accordance with section 1194(f)(4)(B) of the Act and 42 CFR 429.620(g), the same considerations apply for renegotiation.

7. Special Circumstances

There are no special circumstances that would require information collection for the Negotiation Data Elements ICR Form, the Temporary Floor for Small Biotech Drugs ICR Form, or the Counteroffer ICR Form 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.

Negotiation Data Elements ICR Form

Non-FAMP data are proprietary, as are certain other data required under section 1193(c)(1) of the Act. In accordance with section 1193(c) of the Act, information submitted that is proprietary information, as determined by the Secretary, shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out Part E of Title XI of the Act (i.e., the Negotiation Program). Proprietary information, including trade secret and confidential commercial or financial information, would also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act ((FOIA) (5 U.S.C. 552(b)(3), (4)).[13] While CMS neither requests nor requires protected health information (PHI) or personally identifiable information (PII) in this information request, interested parties may potentially submit information considered by CMS to be PHI or PII.

Temporary Floor for Small Biotech Drugs ICR Form

Information collected through the Temporary Floor for Small Biotech Drugs ICR Form may contain proprietary, trade secret, or other confidential information that would require the information to be collected or kept in a manner that requires further explanation in accordance with section 1194(d) of the Act or proposed 42 CFR 429.300.

13 See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

Counteroffer ICR Form

Information collected through the Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form may contain proprietary, trade secret, or other confidential information. In accordance with Section 1193(c) of the Act, information submitted to CMS by a manufacturer of a selected drug that is determined by CMS to be proprietary information of that manufacturer shall be used only by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secret and confidential commercial or financial information, would also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or 4 of the FOIA (5 U.S.C. 552(b)(3), (4)).[14]

8. Federal Register/Outside Consultation

CMS published a 60-day notice, in conjunction with a proposed rule (CMS-4215-P, RIN 0938–AV90), in the Federal Register (91 FR 36236) on June 16, 2026. A crosswalk document describing the proposed changes from the currently approved version of this ICR to the revisions proposed in this 60-day package is included. CMS intends to review any timely, public comments received in response to this revised package and CMS intends to address, as applicable, any such comments via the final rule later this year. CMS will incorporate revisions, as applicable, within the final version of this ICR and submit to OMB for approval.

Outside Consultation
In the development of the Negotiation Data Elements, CMS sought input from other federal agencies. CMS consulted with the VA regarding the Federal Supply Schedule and the Big Four pharmaceutical drug prices and the FDA regarding pharmaceutical drug identifying information, such as NDCs.

In the development of the collection of information to determine eligibility for the Temporary Floor for Small Biotech Drugs ICR Form, which is based on the SBE requirements, on which CMS sought input from other federal agencies, including the Internal Revenue Service.

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents for participation. If CMS determines that a selected drug or drug selected for renegotiation qualifies for the Temporary Floor for Small Biotech Drugs, then CMS will not offer or accept a counteroffer for an MFP that is below the Temporary Floor for Small Biotech Drugs.

The information submitted on the Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form may be used to reach an agreement on the MFP for the selected drug of the Primary Manufacturer. For example, CMS may accept the Primary

14 See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

Manufacturer's Counteroffer or CMS may issue a revised offer for the MFP based on the Primary Manufacturer's Counteroffer submission.

10. Confidentiality

Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secrets and confidential commercial or financial information, will also be protected from disclosure if the proprietary information meets the requirements set forth under Exemption 3 and/or Exemption 4 of the FOIA (5 U.S.C.

552(b)(3), (4)).[15]

As proposed 42 CFR 429.300, CMS is implementing a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information including Exemption 3 and/or Exemption 4 of the FOIA, and that strikes an appropriate balance between (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary. Thus, for an initial price applicability year, CMS will treat information on non-FAMP (as defined in 38 U.S.C. 8126(h)(5)) as proprietary.

Consistent with 42 CFR 429.300, CMS will also treat certain data elements submitted by a Primary Manufacturer of a selected drug or drug selected for renegotiation in accordance with section 1194(e)(1) and section 1194(e)(2) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. CMS will treat R&D costs and recoupment, unit costs of production and distribution, pending patent applications, market data, and revenue and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat prior Federal financial support, approved patent applications, exclusivity, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available as nonproprietary.

Within a Primary Manufacturer's response to a particular data element required in the Drug Price Negotiation ICR, the response may include information that is non-proprietary because it is publicly available or otherwise does not represent trade secrets and confidential commercial or financial information, such as the introductory language within an explanation field of a data element. Additionally, if a Primary Manufacturer provides a Common Technical File or Drug Master File, that is what is commonly titled "a drug dossier," within the manufacturer's submission of data submitted to CMS in accordance with section 1194(e)(2) of the Act, CMS will treat the submission of a drug dossier as proprietary because CMS understands that this type of document is typically not publicly available. In the Primary Manufacturer's submission of information in response to the Drug Price Negotiation ICR, the Primary Manufacturer may

15 See: https://www.justice.gov/oip/doj-guide-freedom-information-act-0.

identify for CMS which information the Primary Manufacturer believes should be withheld from disclosure by CMS consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that are not included in this section as proprietary by CMS.

Pursuant to sections 1195(a)(2) and 1194(f)(4)(B) of the Act and as discussed proposed 42 CFR 429.620(k) and 429.705, CMS is required to publish the explanation of the MFP by March 1 of the calendar year after the selected drug publication date for the initial price applicability year that the drug was selected for negotiation or renegotiation. In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer and the public, the exchange of offers and counteroffers, and the negotiation meetings, if applicable, without sharing any PHI / PII, proprietary information, or other information protected by federal law reported to CMS. CMS may also make high-level comments about the section 1194(e)(1) and section 1194(e)(2) data submitted to CMS that are determined to be proprietary, without sharing any PHI / PII or any proprietary information reported to CMS.

CMS requests that respondents submitting information for this ICR identify if there is information submitted in response to questions pertaining to section 1194(e)(1) and section 1194(e)(2) data that the respondent believes qualifies for Exemption 3 and/or Exemption 4 of the FOIA, if CMS has not already identified such information as proprietary and/or confidential.

11. Sensitive Questions

Temporary Floor for Small Biotech Drugs ICR Form

In order to ensure that all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC are treated as one manufacturer for purposes of applying the Part D Track, the Primary Manufacturer must provide the EIN(s) of the entity that had a CGDP Agreement in effect for the selected drug on December 31, 2021 (that is, the Part D 2021 Manufacturer) (regardless of whether such entity is the Primary Manufacturer or another entity), and the EIN(s) of any members of that entity's controlled group that had a CGDP Agreement in effect on December 31, 2021. If the Primary Manufacturer was acquired after December 31, 2021, the Primary Manufacturer must provide the EIN(s) for the acquiring entity.

In order to ensure that all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC are treated as one manufacturer for purposes of applying the Part B Track, the Primary Manufacturer must provide the EIN(s) of the entity that held the NDA(s) or BLA(s) for the selected drug as of December 31, 2021 (that is, the Part B 2021 Manufacturer) (regardless of whether such entity is the Primary Manufacturer or another entity), and the EIN(s) of any members of that entity's controlled group on December 31, 2021. Additionally, if the Primary Manufacturer was acquired after December 31, 2021, the Primary Manufacturer must provide the EIN(s) for the acquiring entity.

12. Burden Estimates (Hours & Wages)

Negotiation Data Elements ICR Form: A Primary Manufacturer must complete and submit the information requested on the Negotiation Data Elements ICR Form for the purpose of negotiation or renegotiation, as applicable, for a selected drug. The data required from the Primary Manufacturer are outlined in sections 1193(a)(4) and 1194(e)(1) of the Act and proposed 42 CFR 429.100(d), 429.405(a), 429.505(a), and 429.615(b). The Primary Manufacturer must submit information in the CMS HPMS for the NDC-11s of the selected drug, inclusive of any NDC-11s that the Primary Manufacturer submits for the list of NDC-11s pursuant to final guidance. Information submission for factors outlined in section 1194(e)(2) of the Act are voluntary and open to all interested parties. By soliciting input from the public on factors outlined in section 1194(e)(2) of the Act, the intent of this information request is to obtain data from any interested party, including patients and consumers, Part D plan sponsors and Medicare Advantage organizations, Primary and Secondary Manufacturers, manufacturers of therapeutic alternatives for a selected drug, hospitals and health care providers, wholesalers, pharmacies, and researchers.
To derive wage estimates, CMS used data from the Bureau of Labor Statistics' May 2025 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry, when available, to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the Negotiation Data Elements ICR Form.[16] When industry-specific wage estimates were not available, the Bureau of Labor Statistics' May 2025 Occupational Employment and Wage Statistics data for Cross-industry was used. Tables 1-7 below present the estimated hourly median wage, the cost of fringe benefits and overhead, total burden hours, and total cost to submit this form.

Manufacturer-Specific Data

The Primary Manufacturer is best positioned to provide the requested data and the statute provides that manufacturers participating in the Negotiation Program will submit the requested data.

Thus, Primary Manufacturers that have agreed to participate in the Negotiation Program are required to report the information provided for in sections 1193(a)(4) and 1194(e)(1) of the Act and described in proposed 42 CFR 429.100(d), 429.405(a), and 429.505(a). Pursuant to section 1194(f)(4)(B) of the Act and proposed 42 CFR 429.615(b), Primary Manufacturers are required to submit new information on section 1194(e)(1) data elements and data on NDC-11s of the selected drug that may be payable under Part B (if any) but are not covered under Part D, which are necessary to carry out renegotiation. Table 1 presents the estimated hourly median wage, the adjusted hourly wage (inclusive of fringe benefits and overhead), total burden, and total cost to submit the data outlined in the justification section of this supporting statement and the information collection. Although CMS expects Primary Manufacturers to have some of the data readily available for submission, there is some uncertainty to the estimate in Table 1 as some of

16 See May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at: https://www.bls.gov/oes/tables.htm.

the data required may not be readily available and may take time to compile, such as R&D costs that manufacturers have recouped, as required under section 1194(e)(1) of the Act. Additionally, CMS is adding questions in this revised package within Section F (Question 12) and Section G (Questions 27 and 28), which may or may not require the Primary Manufacturer to gather additional information. Given this uncertainty, the burden estimate is provided along with a high estimate and low estimate in Table 2. CMS believes that the range, however, is already sufficient to account for any additional time a Primary Manufacturer may need to spend preparing a response for the new questions in this revised package. With respect to data collection for renegotiation, CMS expects Primary Manufacturers to have some of the data readily available for submission, particularly because the data is responsive to similar questions and reporting metrics used for collection of data required to be submitted in the course of negotiating the MFP and the Primary Manufacturer will be familiar with the process of compiling, calculating, and submitting this data to CMS; however, there is some uncertainty to the estimate in Table 3 as some of the data required may not be readily available and may take time to compile, such as R&D costs that manufacturers have incurred since the periods reflected in their prior submissions required under section 1194(e)(1) of the Act. Given this uncertainty, the burden estimate is provided along with a high estimate and low estimate in Table 4. CMS does not intend for the Primary Manufacturer to provide information in response to this ICR Form that the Primary Manufacturer provided in its original full submission of section 1194(e)(1) data to CMS for the negotiation period in which the selected drug's MFP was negotiated.

Evidence About Alternative Treatments

As previously noted, information on selected drugs and their alternative treatments as specified by section 1194(e)(2) of the Act may be gathered from several sources and submission of such information is voluntary and open to the Primary Manufacturer of a selected drug as well as the public. Where possible, data are used to inform this burden estimate. However, there is considerable uncertainty as interested parties will differ in time spent gathering and submitting data, resources available to each party to submit such data, and other considerations that could impact the burden estimate. CMS is revising the instructions to questions within Section I for clarity and mirroring questions regarding the collection of information regarding therapeutic advance and unmet needs for respondents that may be researchers. However, CMS believes the burden range is already sufficient to account for these revisions.

CMS estimates the burden associated with data collection in two separate estimates below, one estimate for the Primary Manufacturer which includes the mandatory data collection in accordance with sections 1193(a)(4), 1194(e)(1), and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.100(d), 429.405(a), 429.505(a) and 429.615(b), as well as the optional submission of data for factors outlined at 1194(e)(2) of the Act; the second estimate is for interested parties submitting data for factors under 1194(e)(2) of the Act. CMS is soliciting comments on these estimates and assumptions. While data under section 1194(e)(2) of the Act is optional for the Primary Manufacturer, CMS expects the Primary Manufacturer will choose to participate in this submission.

A. Estimated Burden for Primary Manufacturers

Selected Drugs for Negotiation: CMS anticipates collecting data from a Primary Manufacturer in response to Sections A through J of this ICR for up to 20 selected drugs for initial price applicability year 2029, and each initial price applicability year thereafter, for negotiation, which will be collected in the calendar year of the selected drug publication date for each initial price applicability year (consistent with proposed 42 CFR 429.20, 429.100(d), 429.405(a), 429.505(a), and 429.620(b)). For purposes of this information collection, CMS assumes there will be up to 20 Primary Manufacturers, one for each selected drug, and up to 20 drugs selected for negotiation, which represents the statutory maximum. The collection of these data will be a onetime cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug. While a Primary Manufacturer may have multiple selected drugs, CMS assumes that a Primary Manufacturer would require the same time and effort to submit data for each selected drug. The Primary Manufacturer must also gather and submit the data required under the Act on behalf of any Secondary Manufacturer(s)[17] of a selected drug, if applicable.

CMS estimates it will take a business operations specialist or team of business operations specialists, on average, 200 hours, at a cost of $95.06 per hour, to gather cost data and compile required information, as specified in the data elements instructions, such as data on prior Federal financial support, pending and approved patent applications, exclusivities recognized by the FDA and applications and approvals, and market data, and revenue and sales volume data. After the relevant data have been gathered and compiled, it is estimated that it will take an economist or team of economists, on average, 600 hours, at a cost of $119.92 per hour, to perform necessary economic analyses, including the R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs, the selected drug's cost of production and distribution, and other data elements specified in the data element instructions. Although submitting evidence about therapeutic alternatives is optional, this burden estimate assumes that all Primary Manufacturers will choose to perform analyses related to therapeutic advances conferred by the selected drug, the costs of existing alternatives, unmet medical need, and comparative effectiveness.

Once these analyses are performed, CMS estimates that it will take a financial manager, on average, 50 hours, at a cost of $175.98 per hour, to review the results of all the analyses and cost estimates prior to submission to CMS. CMS estimates it will take a lawyer 4 hours, on average, at $285.14 per hour, to review the compiled data submission.

CMS estimates that it will take a cost estimator, on average, 142 hours, at a cost of $82.82 per hour, to compile and report the required data to CMS, per the data element form instructions.

Finally, CMS estimates that it will take a CEO, on average, 4 hours, at $355.30 per hour, to review the data submission and log in to the CMS HPMS to certify the submission. Certification

17 The burden estimate assumes some coordination between the Primary Manufacturer and the Secondary Manufacturer, as necessary, to collect and submit the data.

must be done by (1) the CEO, (2) the CFO, (3) an individual with equivalent authority to a CEO or a CFO of the Primary Manufacturer, or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

The cost estimates for one-time costs are presented in Table 1. The estimate yields a total burden of 20,000 hours (1,000 hrs. per Primary Manufacturer per selected drug * 20 selected drugs) and total cost of $2,281,704.00 for all 20 selected drugs ($114,085.20 per respondent per selected drug * 20 selected drugs).

TABLE 1: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR 20 SELECTED DRUGS FOR ONE INITIAL PRICE APPLICABILITY YEAR

Occupation Title	Hourly Median Wage	Cost per hour*	# Of Hours	# Of Respondents	Total Burden Hours	Total Cost
Financial Manager (113031)	$87.99	$175.98	50	20	1,000	$175,980.00
Cost Estimator (13-1051)	$41.41	$82.82	142	20	2,840	$235,208.80
Business Operations Specialists (131000)	$47.53	$95.06	200	20	4,000	$380,240.00
Economist (19-3011)[18]	$59.96	$119.92	600	20	12,000	$1,439,040.00
Lawyer (231011)	$142.57	$285.14	4	20	80	$22,811.20
Chief Executive (11-1011)	$177.65	$355.30	4	20	80	$28,424.00
Total (20 Manufacturers)	-	-	-	**20**	**20,000**	**$2,281,704.00**
Total per Manufacturer	-	-	-	1	**1,000**	**$114,085.20**

** As previously noted, this estimate assumes 100 percent increase to account for fringe benefits and overhead. This adjustment is a broad approximation as fringe benefits and overhead costs vary significantly across employers and methods of estimating these costs vary widely across studies.*

An additional low estimate and high estimate is provided in Table 2 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 1 "Total Burden Hours" per 1 respondent) has been reduced by half for each labor category. For the high estimate, the required time and cost associated with each labor category from the base estimate has been doubled.

18 Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000 – Cross-industry. Available at: https://www.bls.gov/oes/tables.htm.

TABLE 2: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	500	$57,042.60	$1,140,852.00
Base Estimate (from Table 1)	1,000	$114,085.20	$2,281,704.00
High Estimate	2,000	$228,170.40	$4,563,408.00

Selected Drugs for Renegotiation: CMS anticipates collecting a subset of the data in response to Sections A through J of this ICR from a Primary Manufacturer for a maximum of 36 selected drugs, using initial price applicability year 2029 as the base year, for renegotiation, which will be collected in 2027 for initial price applicability year. For drugs without a change in monopoly status, CMS does not expect that it would be likely that renegotiation would result in a significant change to the agreed-upon MFP for drugs selected for prior initial price applicability years except in unanticipated or unusual circumstances. As such, CMS anticipates that fewer than 36 drugs will be selected for renegotiation for the base year, but CMS cannot provide definitive assumptions about how many drugs may be selected for renegotiation. As additional drugs are selected for negotiation, such as for initial price applicability years 2029 and 2030, additional selected drugs may be eligible for renegotiation. However, due to removal from selection (consistent with proposed 42 CFR 429.130(b)), some drugs selected for negotiation may be removed prior to submission of this ICR. Therefore, we estimate the respondent number based on data available to CMS prior to the base year of initial price applicability year 2029. Further, regardless of the total number of drugs eligible for selection for renegotiation, the collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug. While a Primary Manufacturer may have multiple selected drugs, CMS assumes that a Primary Manufacturer would require the same time and effort to submit data for each selected drug. The Primary Manufacturer must also gather and submit the data required under the Act on behalf of any Secondary Manufacturer(s)[19] of a selected drug, if applicable.

CMS assumes a lower burden for data submissions for drugs selected for renegotiation relative to the original submission of data for negotiation because Primary Manufacturers will need to report only new data for a short period of time in response to this ICR. For example, the Primary Manufacturer will only need to complete Section B for drugs payable under Part B, if applicable, and the Primary Manufacturer will only need to provide new data in Sections C, E and F for a

19 The burden estimate assumes some coordination between the Primary Manufacturer and the Secondary Manufacturer, as necessary, to collect and submit the data.

limited time period, if applicable. All Primary Manufacturers of drugs selected for renegotiation will need to provide data in response to Section G, but for a shorter period of time compared to the original submission. While CMS is adding a new question for Primary Manufacturers of drugs selected for renegotiation only (which is to report the agreed-to MFP for the selected drug from the prior negotiation), CMS believes that the reporting of this information will contribute a nominal amount of time since this information is readily available to the Primary Manufacturer and does not require a new calculation. Therefore, CMS is not revising the burden estimate specifically in response to this new question. CMS estimates it will take a business operations specialist or team of business operations specialists, on average, 150 hours, at a cost of $95.06 per hour, to gather cost data and compile required information, as specified in the data elements instructions, such as new data on prior Federal financial support, pending and approved patent applications, exclusivities recognized by the FDA and applications and approvals, and market data, and revenue and sales volume data. After the relevant data have been gathered and compiled, it is estimated that it will take an economist or team of economists, on average, 450 hours, at a cost of $119.92 per hour, to perform necessary economic analyses, including of new R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped those costs, the selected drug's cost of production and distribution, and other data elements specified in the data element instructions. Although submitting evidence about therapeutic alternatives is optional, this burden estimate assumes that all Primary Manufacturers will choose to perform analyses related to new information on therapeutic advances conferred by the selected drug, the costs of existing alternatives, unmet medical need, and comparative effectiveness.

Once these analyses are performed, CMS estimates that it will take a financial manager, on average, 37.5 hours, at a cost of $175.98 per hour, to review the results of all the analyses and cost estimates prior to submission to CMS. CMS estimates it will take a lawyer 3 hours, on average, at $285.14 per hour, to review the compiled data submission.

CMS estimates that it will take a cost estimator, on average, 106.5 hours, at a cost of $82.82 per hour, to compile and report the required data to CMS, per the data element form instructions.

Finally, CMS estimates that it will take a CEO, on average, 3 hours, at $355.30 per hour, to review the data submission and log in to the CMS HPMS to certify the submission. Certification must be done by (1) the CEO, (2) the CFO, (3) an individual with equivalent authority to a CEO or a CFO of the Primary Manufacturer, or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

The cost estimates for one-time costs are presented in Table 3. The estimate yields a total burden of 27,000 hours (750 hrs. per Primary Manufacturer per selected drug * 36 selected drugs) and total cost of $3,080,300.40 if a maximum of 36 selected drugs are selected for renegotiation ($85,563.90 per respondent per selected drug * 36 selected drugs).

TABLE 3: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR UP TO 37 SELECTED DRUGS FOR ONE INITIAL PRICE APPLICABILITY YEAR

Occupation Title	Hourly Median Wage	Cost per hour*	# Of Hours	# Of Respondents	Total Burden Hours	Total Cost
Financial Manager (113031)	$87.99	$175.98	37.5	36	1,350	$237,573.00
Cost Estimator (13-1051)	$41.41	$82.82	106.5	36	3,834	$317,531.88
Business Operations Specialists (131000)	$47.53	$95.06	150.0	36	5,400	$513,324.00
Economist (19-3011)[20]	$59.96	$119.92	450.0	36	16,200	$1,942,704.00
Lawyer (231011)	$142.57	$285.14	3.0	36	108	$30,795.12
Chief Executive (11-1011)	$117.65	$355.30	3.0	36	108	$38,372.40
Total (37 Manufacturers)	-	-	-	**36**	**27,000**	**$3,080,300.40**
Total per Manufacturer	-	-	-	**1**	**750**	**$85,563.90**

** As previously noted, this estimate assumes 100 percent increase to account for fringe benefits and overhead. This adjustment is a broad approximation as fringe benefits and overhead costs vary significantly across employers and methods of estimating these costs vary widely across studies.*

An additional low estimate and high estimate are provided in Table 4 below to illustrate the possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 3 Total) has been reduced by half for each labor category. For the high estimate, the required time and cost associated with each labor category from the base estimate has been doubled.

20 Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000 – Cross-industry. Available at: https://www.bls.gov/oes/tables.htm.

TABLE 4: COST RANGE ESTIMATES FOR PRIMARY MANUFACTURER

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	375	$42,781.95	$1,540,150.20
Base Estimate (from Table 3)	750	$85,563.90	$3,080,300.40
High Estimate	1,500	$171,127.80	$6,160,600.80

B. Estimated Burden for General Public

To generate burden estimates for a base estimate for one initial price applicability year, CMS reviewed the public feedback that was received for prior initial price applicability years. CMS received up to approximately 300 submissions from individuals and organizations for the section 1194(e)(2) data collection for one prior initial price applicability year. The proportion of the submissions a respondent self-selecting an organization-related category continues to remain slightly higher and more than half compared to respondents self-reporting in an individual category, such as a patient/caregiver. Due to the inclusion of selected drugs for renegotiation and the year-over-year greater awareness around the public input process for the Drug Price Negotiation Program, CMS will maintain the total estimate of responses that may be received as burden estimate for one initial price applicability year (325), which assumes it will receive approximately at most a similar volume of public submissions from highest prior total submissions, with approximately 150 individual respondents and 175 organizations because the proportion of individuals and organizations remained generally consistent across the prior initial price applicability years for which data has been collected thus far.

This estimate assumes as many as 150 individual respondents may spend, on average, 3 hours to review literature and submit information to CMS for a selected drug. Additionally, CMS assumes that there will be other organizations that develop responses that will take additional resources. CMS estimates that as many as 175 organizations may take, on average, 30 hours to review literature and submit information to CMS. The U.S. Bureau of Labor Statistics' labor category of "all occupations" was used for this estimate given individual and organizational labor estimates will vary; the estimate includes overhead and fringe benefits at 100 percent of the hourly wage. This estimate yields a total burden of 5,700 hours ([3 hrs. * 150 respondents] + [30 hrs. * 175 respondents]) and total cost of $279,414.00 ($49.02 * 5,700 hrs.), as displayed in Table 5.

TABLE 5: SUMMARY OF INFORMATION COLLECTION REQUEST FOR PUBLIC FEEDBACK FOR ONE INITIAL PRICE APPLICABILITY YEAR

Type of Respondent	Occupation Title	Hourly Median Wage	Cost Per Hour*	# Of Respondents	Hours per Response	Total Hours	Total Cost
Individual	All Occupations 00-0000	$24.51	49.02	150	3	450	$22,059.00
Organization	All Occupations 00-0000	$24.51	49.02	175	30	5,250	$257,355.00
Total	**-**	**-**	**-**	**325**	**33**	**5,700**	**$279,414.00**

**Includes fringe benefits and overhead of 100 percent of the hourly median wage.*

An additional low estimate and high estimate is provided in Table 6 and Table 7 below to illustrate possible variability for this burden estimate. To calculate the low estimate, the base estimate (Table 5 Total) has been reduced by half for the “individual” and “organization” categories. For the high estimate, the required time and cost associated with individuals and organizations has been doubled.

TABLE 6: COST RANGE ESTIMATES FOR AN INDIVIDUAL FOR PUBLIC FEEDBACK FOR ONE INITIAL PRICE APPLICABILITY YEAR

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	1.5	$73.53	$11,029.50
Base Estimate (from Table 5)	3.0	$147.06	$22,059.00
High Estimate	6.0	$294.12	$44,118.00

TABLE 7: COST RANGE ESTIMATES FOR AN ORGANIZATION FOR PUBLIC FEEDBACK FOR ONE INITIAL PRICE APPLICABILITY YEAR

	Hours per Respondent	Cost per Respondent	Total Cost
Low Estimate	15	$735.30	$128,677.50
Base Estimate (from Table 5)	30	$1,470.60	$257,355.00
High Estimate	60	$2,941.20	$514,710.00

Temporary Floor for Small Biotech Drugs ICR Form: A Primary Manufacturer must complete and submit the information requested on this form in order for CMS to consider whether the selected drug qualifies for the Temporary Floor for Small Biotech Drugs. If the Primary Manufacturer that seeks the Temporary Floor for Small Biotech Drugs for their selected drug was acquired after December 31, 2021, the Primary Manufacturer must also submit information related to the acquiring entity. A Primary Manufacturer may submit the Temporary Floor for Small Biotech Drugs ICR Form for drugs payable under Part B, covered under Part D, or both payable under Part B and covered under Part D.

To identify wage estimates, we used data from the Bureau of Labor Statistics (shown below) to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with completing the Temporary Floor for Small Biotech Drugs ICR Form submission, and recordkeeping.[21]

Occupation Title	Hourly Median Wage	Fringe Benefits and Overhead per Hour	Adjusted Hourly Wage*
Lawyer (23-1011)	$142.57	$142.57	$285.14

21 See May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at https://data.bls.gov/oes/#/industry/325400.

General and Operations Manager (11-1021)	$82.99	$82.99	$165.98
Chief Executive (11-1011)	$177.65	$177.65	$355.30

**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.*

Tables 8 and 9 present the total burden hours/hours per respondent and total cost (based on the adjusted hourly wage as shown above). Table 8 presents total burden, and total cost (based on the adjusted hourly wage as shown above), to submit the data outlined in the justification section of this supporting statement and the information collection. Although CMS expects Primary Manufacturers to have some of the data readily available for submission, there is some uncertainty as to the estimate in Table 8 as some of the data required may not be readily available and may take time to compile and there may be potential variations in burden between a Primary Manufacturer submitting the Temporary Floor for Small Biotech Drugs ICR Form depending on whether the selected drug is solely payable under Part B, solely covered under Part D, or is both payable under Part B and covered under Part D.

Additionally, some Primary Manufacturers may have to submit additional material based on whether the Primary Manufacturer was acquired after December 31, 2021, whether the Primary Manufacturer had a CGDP Agreement in effect for the selected drug on December 31, 2021, and whether the Primary Manufacturer held the NDA(s) and/or BLA(s) for the selected drug on December 31, 2021. Given this variability, the burden estimate is provided along with a high estimate and low estimate in Table 9.

CMS estimates 10 total respondents will submit a Temporary Floor for Small Biotech Drugs ICR Form in one year. We believe that the collection of these data will be a one-time cost for each Primary Manufacturer for each selected drug for which it is seeking to qualify for the Temporary Floor for Small Biotech Drugs for initial price applicability year 2029 or 2030.

CMS estimates it will take a lawyer, on average, 6.5 hours, at a cost per hour of $285.14, to gather and review the relevant IRC provisions (e.g., subsection (a) or (b) of section 52 of the IRC), to identify any controlled group members that as of December 31, 2021, were treated as a single employer with the Part B 2021 Manufacturer and/or the Part D 2021 Manufacturer under subsection (a) or (b) of section 52 of the IRC, and to report the relevant information for these entities. Under the Part B Track of the Temporary Floor for Small Biotech Drugs, such information includes the list of NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer and any member of its controlled group as of December 31, 2021. Under the Part D Track of the Temporary Floor for Small Biotech Drugs, such information includes the unique identifier assigned by CMS (P number) and labeler code(s) owned by the Part D 2021 Manufacturer and any member of its controlled group that had a CGDP Agreement in effect on December 31, 2021. This information must be utilized by CMS when calculating Total Expenditures under Part

B during 2021 for the qualifying single source drugs of the Part B 2021 Manufacturer and any member of its controlled group, or when calculating Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a CGDP agreement in effect on December 31, 2021. We estimate that it will take a general and operations manager, on average, 3 hours, at $165.98 per hour, to examine the gathered information and submit the Temporary Floor for Small Biotech Drugs ICR Form to CMS. We also estimate that it will take a lawyer and a general operations manager, on average, 30 minutes, or 0.5 hours, each to request technical assistance from CMS (totaling six and one half hours for a lawyer in sum and three hours for a general and operations manager in sum). We estimate that it will take a chief executive, on average, 0.25 hours, at $355.30 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) of the Primary Manufacturer, (2) the chief financial officer (CFO) of the Primary Manufacturer, (3) an individual with equivalent authority to a CEO or a CFO of the Primary Manufacturer, or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

The cost estimates for one-time costs are presented in Table 8. The estimate yields a total burden of 97.5 hours (9.75 hrs. * 10 respondents) and total cost of $24,401.75 ($2,440.18 per respondent * 10 respondents).

TABLE 8: SUMMARY OF INFORMATION COLLECTION REQUEST BURDEN FOR SMALL BIOTECH DRUGS FOR A PRIMARY MANUFACTURER FOR THE ONE TIME COST OVER THE ONE-YEAR PERIOD FOR ONE INITIAL PRICE APPLICABILITY YEAR

Respondents' Occupation Title	**# Of Hours per Respondent**	**# Of Respondents**	**Total Burden Hours**	**Total Cost**
Lawyer (23-1011)	6.50	10	65.0	$18,534.10
General and Operations Manager (11-1021)	3.00	10	30.0	$4,979.40
Chief Executive (11-1011)	0.25	10	2.5	$888.25
Respondents' Occupation Title	**# Of Hours per Respondent**	**# Of Respondents**	**Total Burden Hours**	**Total Cost**
Total	**9.75**	**10**	**97.5**	**$24,401.75**

Cost per Respondent	**-**	**-**	**-**	**$2,440.18**

An additional low estimate and high estimate is provided in Table 9 below to illustrate the possible variability for this burden estimate based on the amount of research and review required to answer the collection for a particular drug and based on which scenarios apply to a specific drug (e.g., acquisition). The high and low estimates are intended to capture the varying amount of time that may be needed for a submission that includes a drug solely payable under Part B or solely covered under Part D, or that is both payable under Part B and covered under Part D. To calculate the low estimate, the base estimate (Table 8 "Total # of hours per respondent") has been reduced by half for each labor category. For the high estimate, the required time associated with each labor category from the base estimate has been doubled.

TABLE 9: COST RANGE ESTIMATES OF BURDEN FOR PRIMARY MANUFACTURER FOR THE ONE TIME COST FOR SMALL BIOTECH DRUGS OVER THE ONE-YEAR PERIOD FOR AN INITIAL PRICE APPLICABILITY YEAR

	Hours per Respondent	**Cost per Respondent**	**Total Cost**
Low Estimate	4.875	$1,220.09	$12,200.88
Base Estimate (from Table 8)	9.750	$2,440.18	$24,401.75
High Estimate	19.500	$4,880.35	$48,803.50

Counteroffer ICR Form: A Primary Manufacturer must complete and submit the information requested on the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable, if it both chooses not to accept CMS' initial offer and chooses to submit a Counteroffer for a selected drug. The burden estimate for this information collection is detailed in this section. The Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form are collectively referred to as the "Counteroffer ICR Form" due to CMS approximating the estimates for each form to be similar due to the questions on the forms requiring about the same amount of time for a manufacturer to collect and submit the information on the applicable form.

To derive wage estimates, CMS used data from the Bureau of Labor Statistics' May 2024 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry, when available, to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the

burden associated with the Counteroffer ICR Form.[22] When industry-specific wage estimates were not available, the Bureau of Labor Statistics' May 2024 Occupational Employment and Wage Statistics data was used. Table 8 below presents the estimated hourly median wage, the cost of fringe benefits and overhead, total burden hours, and total cost to submit the form.

CMS will select up to 20 high expenditure, single source drugs payable under Medicare Part B and/or covered under Medicare Part D for negotiation for initial price applicability year 2029 and each initial price applicability year thereafter. Statutory written counteroffers will be submitted by Primary Manufacturers for up to 20 selected drugs, and completing the Statutory Written Counteroffer ICR Form will be a one-time cost for each selected drug for which a Primary Manufacturer submits a statutory written counteroffer. The statute envisions that statutory written counteroffer submissions for an initial price applicability year will occur in the calendar year of the selected drug publication date for such initial price applicability year, as the statute instructs CMS to make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug no later than June 1 of such calendar year of the selected drug publication date for such initial price applicability ear, and if the Primary Manufacturer chooses to submit a statutory written counteroffer, the statute provides that it must do so no later than 30 days after the date of receipt of the written initial offer. Renegotiation written counteroffers will be submitted by Primary Manufacturers for a maximum of 36 selected drugs for one initial price applicability year, using initial price applicability year 2029 as the base year (see additional discussion regarding the potential number of drugs selected for renegotiation and correspondent respondents within the burden estimate for Negotiation Data Elements ICR Form), and completing the Renegotiation Written Counteroffer ICR Form will be a one-time cost for each selected drug for which a Primary Manufacturer submits a renegotiation written counteroffer. Pursuant to section 1194(f)(4)(B) of the Act and proposed 42 CFR 429.620(b), the deadlines for CMS to make a written initial offer to the Primary Manufacturer and for the Primary Manufacturer to submit a Counteroffer, if applicable, are the same for the renegotiation process as for the negotiation process. CMS assumes each Primary Manufacturer will spend, on average,

the same amount of time to develop and submit Counteroffer information for each selected drug. While a Primary Manufacturer may have multiple selected drugs, CMS assumes that the Primary Manufacturer would require the same time and effort to submit Counteroffer information for each selected drug.

CMS estimates up to 56 total respondents for one initial price applicability year, using initial price applicability year 2029 as the base year. CMS chose this number because by statute only up to 20 drugs payable under Medicare Part B and/or covered under Medicare Part D can be selected for negotiation for 2029 and a maximum of 36 drugs can be selected for renegotiation for 2029 (see again burden estimate discussion above), and for each selected drug CMS will undergo negotiation or renegotiation with only one Primary Manufacturer, so it is not possible that there would be more than 56 respondents for one initial price applicability year, using initial price applicability year 2029 as the base year.

---

22 See May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 - Pharmaceutical and Medicine Manufacturing. Available at https://data.bls.gov/oes/#/industry/325400.

CMS expects the Primary Manufacturer will have a team preparing the Counteroffer ICR Form. CMS expects this team to consist of chief executives, lawyers, health care professionals, economists, general and operations managers, and business operation specialists. The estimate below accounts for the burden of preparing and submitting the Counteroffer ICR Form.

- CMS estimates it will take a business operation specialist, or a team of business operations specialists, 27.00 hours, on average, at $95.06 per hour, to review CMS' initial offer and justification and compare it to current prices, revenue, and other market and clinical data for the selected drug. CMS also expects this business operation specialist, or team, to compare CMS' justification with the data the Primary Manufacturer submitted as part of the section 1194(e)(1) and (2) factors and the section 1194(e)(2) data from other interested parties shared by CMS with the Primary Manufacturer, if feasible, and put together recommendations on how the initial offer compares to what was submitted and develop Counteroffer options and justifications.
- CMS estimates it will take a team of healthcare professionals, such as doctors, advanced practice nurses/nurses, and/or pharmacists, 25.00 hours, on average, to compare CMS' initial offer and justification to the section 1194(e)(2) factors around the selected drug and therapeutic alternatives and develop Counteroffer options and justifications. CMS estimates these 25.00 hours will be divided into 15.00 hours (on average, at $133.46 per hour) for pharmacists, 5.00 hours (on average, at $71.14 per hour) for nurses, and 5.00 hours (on average, at $246.70 per hour) for doctors.
- CMS estimates it will take an economist, or team of economists, 64.00 hours, on average, at $119.92 per hour, to consider team recommendations of the business operations specialist(s) and healthcare professionals, model counteroffer options, and recommend Counteroffer options.
- CMS estimates it will take a general or operations manager, or a team of general or operations managers, 14.25 hours, on average, at $165.98 per hour, to review Counteroffer options and justifications, develop a Counteroffer proposal for the MFP, and to examine the gathered information, populate the Counteroffer ICR Form, and submit the Counteroffer ICR Form to CMS.

- CMS estimates it will take a lawyer, or team of lawyers, 64.00 hours, on average, at $285.14 per hour, to review counteroffer options and draft a justification for the selected Counteroffer proposal for the MFP.
- CMS estimates it will take a Chief Executive, on average, 10.00 hours, at $355.30 per hour, to review the Counteroffer proposal for the MFP, make a decision on the Counteroffer proposal for the MFP, review the Counteroffer information prior to submission, and log in to the CMS HPMS to certify the submission. Certification must be done by (1) the CEO, (2) the CFO, (3) an individual with equivalent authority to a CEO or a CFO of the Primary Manufacturer, or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

The cost estimates for one-time costs are presented in Table 10 below. The estimate yields a total burden of 11,438 hours (204.25 hrs.* 56 respondents) and total cost of $2,127,987.40 ($37,999.78 per respondent * 56 respondents).

TABLE 10: SUMMARY OF INFORMATION COLLECTION FOR DEVELOPING A COUNTEROFFER ICR FORM SUBMISSION PER SELECTED DRUG, FOR THE ONETIME COST OVER THE ONE-YEAR PERIOD

Occupation Title	Hourly Median Wage	Cost per hour*	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Business Operations Specialists (13-1000)	$47.53	$95.06	27.00	56	1,512	$143,730.72
Pharmacists (29-1051)	$66.73	$133.46	15.00	56	840	$112,106.40
Registered Nurses (29-1141)	$35.57	$71.14	5.00	56	280	$19,919.20
General Internal Medicine Physicians (29-1216) [23]	$123.35	$246.70	5.00	56	280	$69,076.00

Occupation Title	Hourly Median Wage	Cost per hour*	# Of Hours per Respondent	# Of Respondents	Total Burden Hours	Total Cost
Economist (19-3011) [24]	$59.96	$119.92	64.00	56	3,584	$429,793.28
General and Operations Managers (11-1021)	$82.99	$165.98	14.25	56	798	$132,452.04

23 Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000 – Cross-industry. Available at: https://www.bls.gov/oes/tables.htm.

24 Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000 – Cross-industry. Available at: https://www.bls.gov/oes/tables.htm.

Lawyer (231011)	$142.57	$285.14	64.00	56	3,584	$1,021,941.76
Chief Executive (11-1011)	$177.65	$355.30	10.00	56	560	$198,968.00
Total	-	-	**204.25**	**56**	**11,438**	**$2,127,987.40**
Cost per Respondent	-	-	-	-	-	**$37,999.78**

**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.*

13. Capital Costs

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

14. Cost to Federal Government

To generate salary estimates reflected in Tables 11–13 below, CMS used the 2026 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington region.[25] In this regard, Tables 11–13 present the FullTime Equivalent (FTE) of staff required for the task, the adjusted hourly wage, which is the hourly basic rate plus the cost of fringe benefits (calculated at 100 percent of salary), total burden hours, and the total cost of the information collection. Staffing estimates are based on CMS duties as follows:

Negotiation Data Elements ICR Form

The federal government cost is based on the efforts expended by CMS staff with the following assumptions to receive, review, and process data from drug manufacturers and the public for the negotiation and renegotiation processes. Staffing estimates are based on CMS duties as follows:

- CMS will review and analyze information submitted by Primary Manufacturers and the public in the Negotiation Data Elements ICR Form to inform initial offers; and
- CMS will provide technical direction to a contractor to modify the Drug Price Negotiation module in the CMS HPMS for Primary Manufacturers and the public to submit the Negotiation Data Elements ICR Form.

In addition, CMS staff and contracted workers will complete work and need modifications of the existing system in the CMS HPMS to accommodate this ICR.

25 See: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2026/DCB_h.pdf.

TABLE 11. BURDEN ESTIMATE COST FOR CMS STAFF FOR ONE INITIAL PRICE APPLICABILITY YEAR FOR NEGOTIATION DATA ELEMENTS ICR FORM

Staff	FTE Equivalent	Hourly Wage*	Total Burden Hours	Total Cost
Section 1194(e) Review				
GS-13, step 1	8	$116.70	1,566	$182,752.20
GS-14, step 1	3	$137.92	1,566	$215,982.72
GS-15, step 1	2	$162.22	398	$64,563.56
Modification of the Existing CMS HPMS				
GS-13, step 1	2	$116,702	100	$13,792.00
Contractor	4.5	$249.59	350	$87,356.50
Total Cost to Government Over One Year				**$564,446.98**

** As previously noted, this estimate assumes a 100 percent increase to account for fringe benefits and overhead. This adjustment is a broad approximation as fringe benefits and overhead costs vary significantly across employers and methods of estimating these costs vary widely across studies.*

Temporary Floor for Small Biotech Drugs ICR Form

The federal government cost is based on the efforts expended by CMS staff with the following assumptions to receive, review, and process data from drug manufacturers for the Temporary Floor for Small Biotech Drugs ICR Form submissions, implementing the Temporary Floor for Small Biotech Drugs for selected drugs that qualify, technical operations, and IT builds. Staffing estimates are based on CMS duties as follows:

- CMS will review information submitted by Primary Manufacturers in the Temporary Floor for Small Biotech Drugs ICR Form to determine if a selected drug qualifies for the Temporary Floor for Small Biotech Drugs; and
- CMS will calculate the Temporary Floor for Small Biotech Drugs for all selected drug(s) that qualify for the Temporary Floor for Small Biotech Drugs and inform the Primary Manufacturer(s);

In addition, CMS staff may also need to communicate with the Primary Manufacturers of small biotech drugs. CMS staff and contracted workers will complete work modifications of the existing system in the CMS HPMS to accommodate this ICR. CMS staff will provide technical direction to a contractor to complete work within CMS HPMS to accommodate the Temporary Floor for Small Biotech Drugs ICR Form.

TABLE 12. BURDEN ESTIMATE COST FOR CMS STAFF FOR ONE INITIAL PRICE APPLICABILITY YEAR FOR THE TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS ICR FORM

Staff	FTE Equivalent	Hourly Wage*	Total Burden Hours	Total Cost
Temporary Floor for Small Biotech Drugs Review				
GS-13, step 1	1	$116.70	60	$7,002.00
GS-14, step 1	1	$137.92	16	$2,206.72
GS-15, step 1	1	$162.22	4	$648.88
Communicating with Small Biotech Drug Primary Manufacturers				
GS-13, step 1	1	$116.70	16	$1,867.20
GS-14, step 1	1	$137.92	4	$551.68
GS-15, step 1	1	$162.22	1	$162.22
Modification of the Existing CMS HPMS				
GS-13, step 1	1	$116.70	120	$14,004.00
Contractor	1	249.59	920	$229,622.80
Total Cost to Government Over One Year				**$256,065.50**

** As previously noted, this estimate assumes a 100 percent increase to account for fringe benefits and overhead. This adjustment is a broad approximation as fringe benefits and overhead costs vary significantly across employers and methods of estimating these costs vary widely across studies.*

Counteroffer ICR Form

The federal government cost estimate is based on the efforts expended by CMS staff with the following assumptions to receive and review Counteroffer submissions from Primary Manufacturers and technical operations and IT builds. Staffing estimates are based on CMS duties as follows:

- CMS will review and analyze information submitted by Primary Manufacturers in the Counteroffer ICR Form to inform negotiations or renegotiations; and
- CMS will provide technical direction to a contractor to modify the Drug Price Negotiation module in the CMS HPMS for Primary Manufacturers to submit the Counteroffer ICR Form.

In addition, CMS staff and contracted workers will complete work and need modifications of the existing system in the CMS HPMS to accommodate this ICR.

TABLE 13. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT THE COUNTEROFFER PROCESS FOR SELECTED DRUGS

Staff	FTE Equivalent	Hourly Wage*	Total Burden Hours	Total Cost
Counteroffer Review				
GS-13, step 1	5	$116.70	638	$74,454.60
GS-14, step 1	5	$137.92	638	$87,992.96
GS-15, step 1	2	$162.22	172	$27,901.84
Senior Executive Service	1	$184.54	86	$15,870.44
Modification of the Existing CMS HPMS				
GS-13, step 1	1	$116.70	60	$7,002.00
Contractor	2	$249.59	100	$24,959.00
Total Cost to Government Over One Year				**$238,180.84**

** As previously noted, this estimate assumes a 100 percent increase to account for fringe benefits and overhead. This adjustment is a broad approximation as fringe benefits and overhead costs vary significantly across employers and methods of estimating these costs vary widely across studies.*

TABLE 14. TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE NEGOTIATION DATA ELEMENTS ICR, SMALL BIOTECH ICR FORM, AND COUNTEROFFER ICR FORM

Task	**Estimated Cost**
Negotiation Data Elements ICR	$564,446.98
Task	**Estimated Cost**
Temporary Floor for Small Biotech Drugs ICR Form	$256,065.50
Counteroffer ICR Form	$238,180.84
Total Cost to Government Over 1 Year	**$1,058,693.32**

15. Changes to Burden

This is a revision of a currently approved ICR.

CMS includes technical revisions to the Negotiation Data Elements ICR Form that are listed in the accompanying crosswalk of changes between the currently approved package and this 60-day package.

CMS is proposing the following substantives changes to the Negotiation Data Elements ICR Form that impact the burden of a Primary Manufacturer to respond to the ICR because CMS is requesting the additional following information; however, CMS discusses in further detail under Section 12: Burden Estimates how the specific questions are incorporated into the range of the previously approved burden estimates:

- Section F, Question 12: The predicted loss of exclusivity for the selected drug;
- Section G, Question 27: The payer mix by indication for the selected drug; and
- Section G, Question 28: For drugs selected for renegotiation, the agreed-to MFP for the selected drug.

In the Negotiation Data Elements ICR Form and the Counteroffer Process ICR Form, CMS revised the references to specific dates to include references to the defined terms included with proposed 42 CFR 429.20. These revisions do not impact the burden.

CMS included a new burden estimate for a Primary Manufacturer's voluntary completion of the Temporary Floor for Small Biotech Drugs ICR Form.

A crosswalk describing the revisions to this 60-day ICR package is attached.

In sum, the hourly burden difference and cost impact between the currently approved version and this proposed 60-day version are included in Table 15 below.

TABLE 15. COMPARISON OF CURRENTLY APPROVED ICR COMPARED TO THE 60-DAY PROPOSED REVISIONS

Item	Total for Currently Approved ICR	Total for Proposed 60-Day Revisions	Total Difference
Total Number of Respondents	405	447	42
Total Hourly Burden	47,620	64,235.50	16,615.50
Total Cost Per Respondent	$218,231.38	$241,706.71	$23,475.33

Finally, CMS revised the burden estimate to the federal government to account for the addition of the Temporary Floor for Small Biotech Drugs ICR Form and updated the wage amounts used for the staff, which account for the most up-to-date year that is available. In sum, the estimated cost differences between the currently approved version and the changes in this proposed 60-day version are included in Table 16 below.

TABLE 16. COMPARISON OF CURRENTLY APPROVED ICR COMPARED TO THE PROPOSED 60-DAY REVISIONS: TOTAL COST FOR THE FEDERAL GOVERNMENT ASSOCIATED WITH THE DATA COLLECTION TO SUPPORT REVIEW OF THE NEGOTIATION DATA ELEMENTS ICR FORM, TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS ICR FORM, AND COUNTEROFFER ICR FORM

Task	Estimated Cost for Currently Approved ICR	Estimated Cost for Proposed 60-Day Revisions
Negotiation Data Elements ICR Form	$2,633,270.37	$564,446.98
Temporary Floor for Small Biotech Drugs ICR Form	------	$256,065.50
Counteroffer ICR Form	$932,518.32	$238,180.84

Total Cost to Government Over 1 Year	**$3,565,788.69**	**$1,058,693.32**
Total Difference in the Total Cost to Government Over 1 Year	**------**	**-$2,507,095.37**

16. Publication/Tabulation Dates

Pursuant to section 1195(a)(2) of the Act and proposed 42 CFR 429.620(k) and 429.705, CMS will publish an explanation for the MFP with respect to the factors in section 1194(e) of the Act. Therefore, summarized or redacted information may be shared with the public. In this public explanation and any other public documents discussing the MFP, CMS will make public the section 1194(e)(1) and section 1194(e)(2) data submitted by the Primary Manufacturer and the public that are determined to be non-proprietary, but will not include any PHI or PII (see proposed 42 CFR 429.300).

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.