Drug Price Negotiation for Initial Price Applicability Year 20XX
Under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR)
Crosswalk of Changes Between Initial Price Applicability Year 2028 Final Documents and Initial Price Applicability Year 20XX Final Documents*

Location of Edits	Summary of Changes (Included in Final)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Supporting Statement				
Throughout	• Updated references to reflect policies codified in the Negotiation Program final rule (CMS-4215-F) (hereinafter, the "final rule") • Revised instructions for certification to include "Authorized Representative" as defined in the final rule • Revisions to amend initial price applicability year references from "initial price applicability year 2028" to "initial price applicability year 20XX" and/or references to terms in the final rule (e.g., calendar year prior to the selected drug publication date for the applicable initial price applicability year) because CMS intends to incorporate non-substantive date revisions to within the ICR Forms upon review and approval of the package from the Office of Management and Budget annually for each initial price applicability year • Addition of information to incorporate the Small Biotech Floor ICR Form, pursuant to section 1194 of the Social Security Act (the "Act")	Modify	Revisions consistent with the statutory requirements at section 1194 of the Act; Technical updates	Yes
Section A	• Clarified date of service period for calculating Total Expenditures	Modify	Technical update	No
Burden Estimate	• Addition of burden for the Temporary Floor for Small Biotech Drugs ICR Form • Revision of the number of respondents estimated for the Negotiation Data Elements and the Counteroffer Process ICR Forms based on an increase in the statutory maximum number of drugs which could be selected for a given year, starting in initial price applicability year 2029, and the number of selected drugs that may be potentially selected for renegotiation for one year of submission based on the example of initial price applicability year 2029 as the base year • Revisions to update the burden estimates for submitters to incorporate the average labor costs using the May 2025 data from the Bureau of Labor Statistics • Revisions to update the government burden estimate to incorporate 2026 federal pay scales	Modify	Revisions consistent with the statutory requirements at section 1194 of the Act; Technical updates	Yes

Location of Edits	Summary of Changes (Included in Final)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
	• Revisions to update table numbers and formatting of government cost estimate tables			
Information Collection Request (ICR) Forms				
ICR Form – Negotiation Data Elements				
Throughout	• Updated references and definitions to reflect policies codified in the final rule • Standardized format for reporting calendar quarters to YYYY-QN • Revisions to update calendar year references to include placeholder dates applicable to the collection of information for each initial price applicability year (e.g., 20XX) and/or references to terms in the final rule (e.g., calendar year prior to the selected drug publication date for the applicable initial price applicability year) • Renumbering of questions due to revisions in Sections F and G	Modify	Revisions consistent with the statutory requirements at section 1194 of the Act; Technical updates	No
Sections A and F	• Corrected wording error in Section A for consistency and alignment with the final rule • Revision to the instructions in Question 12 to specify that 6,000 characters is approximately 500 words • Added instruction to specify what unit one EA represents in the written response in Questions 13	Modify	Technical updates, Changes in response to comments	No
Sections C and E	• Revisions to streamline questions 1, 2, 3, 6, and 7 for a drug selected for renegotiation with no revenue to report • Clarified which agreements between the Primary Manufacturer and Federal government agencies should be included for drugs selected for renegotiation • Revision to specify that the instruction related to research and development (R&D) costs incurred on or before the last date of the Primary Manufacturer's original full submission of section 1194(e)(1) data applies to any Primary Manufacturers of drugs originally selected for negotiation for initial price applicability years 2026 or 2027 only	Modify	Changes due to internal or administrative review; Technical updates	No
Sections D, F and G	• Addition of instructions to specify the time period of data requested for drugs originally selected for negotiation for the drugs selected for the most recent prior initial price applicability year (which is initial price applicability year 2028) • Deleted "inhaler" from the list of examples for the NCPDP BUS unit of EA in Question 13	Modify	Revisions consistent with the statutory requirements at sections 1194(e)(1)	No

Location of Edits	Summary of Changes (Included in Final)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
	• Addition of instructions that, in cases where the NCPDP Unit is "EA," to specify the unit of measure represented by one "EA" in the Explanation of Unit response in Questions 13 and 23		and (f)(4) of the Act; Changes in response to comments	
Section F	• Revisions to the response format for Questions 9A, 9B and 10 to accommodate text responses in the patent type • Addition of Question 12 regarding the predicted loss of exclusivity for the selected drug	Modify	Revisions consistent with the statutory requirements at sections 1192(e)(1) and (f)(4) of the Act; Changes in response to comments; Technical changes	Yes (regarding addition of question only)
Section G	• Revisions to the numbering of questions throughout the section • Revisions to the instructions for reporting Average Sales Price (ASP) in response to Question 14 when a drug is not payable under Part B • Addition of Question 27 regarding the payer mix of prescriptions for the selected drug by indication • Addition of Question 28 to report the agreed-to maximum fair price of the selected drug from the original negotiation • Revisions to definitions in Section G to clarify meaning of "Manufacturer Medicare Part D average net unit price" and "Manufacturer Medicare Part D average net unit price – best"	Modify	Changes due to internal or administrative review; Changes in response to comments	Yes (regarding addition of questions only)
Section H	• Revisions to instructions for certification to include "Authorized Representative" as defined in the final rule	Modify	Technical update	No
Section I	• Revisions to streamline General Instructions for Section I • Revisions to individual question instructions to include references to supporting citations as applicable • Clarifying revisions to question prompts for Questions 31, 32, 33, 34, 40, 41, 45, 46, 48, 52 • Addition of Question 35 to report medical needs related to condition(s)	Modify	Revisions consistent with the statutory requirements at section 1194(e)(2)(A); Technical updates	Yes (regarding addition of questions only)

Location of Edits	Summary of Changes (Included in Final)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
	• Addition of Question 55 to request therapeutic advance and unmet medical need from researcher respondents • Addition of costs associated with therapeutic alternatives for Question 41 • Removed redundant footnote 46			
ICR Form – Temporary Floor for Small Biotech Drugs				
Throughout	• Addition of the form pursuant to section 1194 of the Act	Modify	Revisions consistent with the statutory requirements at section 1194 of the Act	Yes
ICR Form – Counteroffer Process				
Throughout	• Updated references to reflect policies codified in the final rule • Revisions to update calendar year references to include placeholder dates applicable to the collection of information for each initial price applicability year (e.g., 20XX) and/or references to terms in the final rule (e.g., calendar year prior to the selected drug publication date for the applicable initial price applicability year)	Modify	Technical updates	No
Instructions	• Revisions to the instructions to clarify submission requirements for citations and visual representations • Revisions to instructions for certification to include "Authorized Representative" as defined in the final rule	Modify	Technical updates	No
Question 2	• Revisions to Question 2 to remove the response field for submission of citations and visual representations • Addition of Question 3 and 4 for submission of citations and visual representations, respectively	Modify	Technical updates	No

*Question numbering matches final document.