Negotiation Program Drug Selection 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 – Part A				
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 of the Biosimilar Manufacturer" or "Authorized Representative of the Primary Manufacturer," as applicable and as defined in the final rule • Removal of references to the information collection for a request for a Small Biotech Exception (in accordance with section 1192(d)(2) of the Social Security Act (the Act)) because the statutory provision expired with drug selection for initial price applicability year 2028 • 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 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	Add/Modify	Revisions consistent with the statutory requirements at section 1192(d)(2) of the Social Security Act (the "Act"); Technical updates	Yes
Burden Estimate	• Revision of the number of respondents estimated for the Identification and Selection of Renegotiation-Eligible Drugs ICR Form based on the number of selected drugs that may be potentially eligible for one year of submission based on the example of initial price applicability year 2029 • 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 sections 1194(f)(1) and (4) of the Act; Technical updates	Yes

	• Revisions to update table numbers and formatting of government cost estimate tables			
Request for a Small Biotech Exception				

Location of Edits	Summary of Changes (Included in final)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Form	• Removal of request for a Small Biotech Exception form	Modify	Revisions consistent with the statutory requirements at section 1192(d)(2) of the Act	Yes
Request for a Biosimilar Delay				
Throughout	• 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 update	No
Question 5	• Removed "(123456)" from the "Application Number" question field to streamline and improve clarity	Modify	Technical update	No
Questions 5, 8, and 9	• Addition of examples of the placeholder dates included using initial price applicability year 2029 as the example	Modify	Technical updates	No
Instructions	• Revised to clarify that CMS will deem an Initial Delay Request to be incomplete if it does not include the specified documentation, as applicable • Corrected references to question numbers • Revised instructions for certification to include "Authorized Representative of the Biosimilar Manufacturer" as defined in the final rule	Modify	Technical updates	No
Identification and Selection of Renegotiation-Eligible Drugs Form				
Throughout	• Revisions to update calendar year references to include placeholder dates applicable to the collection of information for each initial price applicability year	Modify	Technical updates	No

	(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)			
Sections 1 and 3	• 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	Technical update	No
Location of Edits	**Summary of Changes (Included in final)**	**Type of Change**	**Explanation of Changes**	**Burden Change (Yes/No)**
Sections 2, 4 and 5	• Addition of instructions to specify the time period of data requested for drugs originally selected for negotiation for initial price applicability year 2028 • Revised Question 11 to clarify that an approval date entry is not required if approval pending	Modify	Revisions consistent with the statutory requirements at sections 1194(e)(1) and (f)(4) of the Act; Technical update	Yes
Instructions	• Revised instructions for certification to include "Authorized Representative of the Primary Manufacturer" as defined in the final rule • Standardized format for reporting calendar quarters to YYYY-QN	Modify	Technical updates	No

*References to question numbering align with final version.