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 20XX ICR and Revised 60-day Version Documents*

Location of Edits	Summary of Changes (Included in 60-day Version of ICR)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Supporting Statement – Part A				
Throughout	• 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 include citations to the Negotiation Program notice of proposed rulemaking (CMS-4215-P) (hereinafter, the "Negotiation Program NPRM") in lieu of cross-references to the Negotiation Program guidance • Revisions to amend initial price applicability year references from" initial price applicability year 2028" to "initial price applicability year 20XX" and/or references to NPRM terms (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 • Revisions to update table numbers and formatting of government cost estimate tables	Modify	Revisions consistent with the statutory requirements at sections 1194(f)(1) and (4) of the Act; Technical updates	Yes
Request for a Small Biotech Exception				
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

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Request for a Biosimilar Delay				
Throughout	• Revisions to include citations to the Negotiation Program NPRM in lieu of cross-references Negotiation Program guidance • 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 NPRM terms (e.g. calendar year prior to the selected drug publication date for the applicable initial price applicability year)	Modify	Technical updates	No
Questions 5, 8, and 9	• Addition of examples of the placeholder dates included using initial price applicability year 2029 for the example	Modify	Technical updates	No
Identification and Selection of Renegotiation-Eligible Drugs Form				
Throughout	• Revisions to include citations to the Negotiation Program NPRM in lieu of cross-references to Negotiation Program guidance • 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 NPRM terms (e.g. calendar year prior to the selected drug publication date for the applicable initial price applicability year)	Modify	Technical updates	No
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 updates	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	Modify	Revisions consistent with the statutory requirements at sections 1194(e)(1) and (f)(4) of the Act	Yes

Location of Edits	Summary of Changes (Included in 60-day Version of ICR)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Section 6	• Revision to the time period for the data requested from the last agreed-to maximum fair price through December 31, 2025 and revised to the last offer from either CMS or the Primary Manufacturer for the initial price applicability that the drug was originally selected for negotiation through the due date of this ICR • The ordering of Questions 14 and 15 is switched (the previous Question 14 is currently Question 15 and the previous Question 15 is currently Question 14) • Revisions to Questions 14 and 15 to align with the description of off-label uses included in proposed 42 CFR 429.605	Modify	Revisions consistent with the statutory requirements at sections 1194(e)(1) and (f)(4) of the Act; technical updates	No

*References to question numbering align with proposed 60-day version.