Negotiation Program Drug Selection for Initial Price Applicability Year 2028
under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR):
Crosswalk of Changes Between Initial Price Applicability Year 2027 Final ICR and Initial Price Applicability Year 2028 60-Day ICR Documents

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Supporting Statement – Part A				
Throughout	• Revisions to incorporate reference to the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and 2028 (hereinafter, the "draft guidance") • Revisions to address the inclusion of the Identification and Selection of Renegotiation-Eligible Drugs ICR Form within this package • Revisions to address the inclusion of drugs payable under Part B for small biotech exception (SBE) requests • Revisions to align with the draft guidance	Add/Modify	Technical updates related to updating program guidance references; Revisions and additions to address statutory requirements at sections 1192(d)(2)(A) and 1194(f) of the Social Security Act (the "Act")	Yes
Federal Register	• Revisions to capture that the initial price applicability year 2028 materials are being published for a new 60-day comment period	Add/Modify	Technical update	No

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Burden Estimates	• Revisions to the SBE manufacturer burden estimate, including for manufacturers with drugs payable under Part B • Revisions to the Biosimilar Delay government burden estimate • Addition of burden estimates to capture the inclusion of the Identification and Selection of Renegotiation-Eligible Drugs ICR Form for initial price applicability year 2028, including a request for public comment regarding the ICR Form instructions on the time period of the data requested • Updated government burden estimate to account for 2025 salary and benefits data	Modify	Technical updates; Revisions to capture burden changes related to ICR Form revisions within the Centers for Medicare & Medicaid Services Health Plan Management System (the "CMS HPMS") module; Additions to address statutory requirements at sections 1192(d)(2)(A) and 1194(f) of the Act	Yes
Changes to Burden	• Addition of language to capture revisions in the 60-day package	Add/Modify	Technical update	No
Information Collection Forms				
Throughout	• Revisions to incorporate reference to the draft guidance	Modify	Technical update	No
Small Biotech Exception				
Instructions	• Revisions to update the CMS HPMS technical access materials • Revisions to address the inclusion of drugs payable under Part B for SBE requests	Add/Modify	Technical update; Revisions and additions to address statutory requirements at section 1192(d)(2)(A) of the Act	No

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Section A	• Revisions to separate questions that are applicable to both drugs payable under Part B and covered under Part D • Technical revisions to clarify terms used in Questions 1-3 • Removal of collection of "labeler code" in Questions 1 and 2	Modify	Technical updates; Revisions to address statutory requirement at section 1192(d)(2)(A) of the Act; Administrative changes based on lessons learned from review of initial price applicability year 2027 submissions	Yes
Section B	• Revisions to separate questions specific to drugs covered under Part D and renumbering of questions • Addition of instructions for section • Technical revisions to the collection of "labeler code(s)" in Questions 4 and 5	Modify	Technical updates	No
Section C	• Revisions to add questions specific to drugs payable under Part B	Modify	Additions to address statutory requirement at section 1192(d)(2)(A) of the Act first relevant for initial price applicability year 2028	Yes
Section D	• Addition of attestation that the individual completing the ICR form is authorized to make the request for the Submitting Manufacturer • Addition of language to identify the statutory authority for civil monetary penalties (CMPs) pertaining to false information	Modify	Administrative change based on lessons learned from review of initial price applicability year 2027 submissions; Technical update	No
Biosimilar Delay				

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Instructions	• Revisions to update the CMS HPMS technical access materials • Clarification that character counts include spaces • Revision to make the request for information related to Biologics License Application (BLA) singular instead of plural to conform with statutory language regarding the application for the Biosimilar (see section 1192(f)(1)(A) of the Act)	Modify	Technical updates	No
Question 1	• Removal of labeler code as a field for identifying information	Modify	Administrative change based on lessons learned from review of initial price applicability year 2027	No
Question 3 and 5 and Certification	• Revisions to request a singular BLA application submission information	Modify	Technical updates	No
Question 9	• Addition of instructions to move to Question 10, only if the Biosimilar Manufacturer selects Option A in Question 9	Modify	Technical updates	Yes
Questions 3 and 10	• Removal of two columns from the table in Question 3 asking if licensing and marketing were planned prior to February 1 of the applicable year • Removal of Option C in Question 10 that would state that the Biosimilar Manufacturer does not expect the Biosimilar to be marketed by February 1 of the applicable year • Revisions to Option B in Question 10 to provide the option to state that the Biosimilar has not yet been marketed	Modify	Administrative change based on lessons learned from review of initial price applicability year 2027, the information requested in the prior version was conclusory and duplicative of more detailed information sought with respect to the high likelihood of marketing prior to the statutory deadline	No

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Question 12	• Inclusion of explanation of supporting documentation	Modify	Technical update	No
Section 4	• Addition of an attestation that the individual completing the ICR form is authorized to make the request for the Biosimilar Manufacturer • Addition of language to identify the statutory authority for CMPs pertaining to false information	Modify	Administrative changes based on lessons learned from review of initial price applicability year 2027; Technical update	No
Selection of Renegotiation-Eligible Drugs				
Throughout	• Addition of instructions and questions that a Primary Manufacturer may voluntarily provide to CMS for consider in CMS' identification and selection of renegotiation-eligible drugs for initial price applicability year 2028	Add/Modify	Additions to address statutory requirements at section 1194(f) of Act first relevant in initial price applicability year 2028	Yes