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 2028 60-day ICR and Initial Price Applicability Year 2028 30-Day ICR Documents

Location of Edits	Summary of Changes (Included for 30-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: Final 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 "final guidance") and to align with definitions and other terms used in the final guidance	Modify	Technical updates related to updating program guidance references and to align with the final guidance	No
Use of Information Technology	• Revisions to capture submission process for Identification and Selection of Renegotiation-Eligible Drugs ICR Form, which will include a template provided by CMS to include the questions and tables only	Modify	Technical updates	No
Federal Register	• Revisions to capture that the initial price applicability year 2028 materials are being published for a 30-day comment period	Modify	Technical update	No
Burden Estimates	• Revisions to update burden estimates to use May 2024 Bureau of Labor Statistics' Occupational Employment and Wage Statistics data (from May 2023 data) • Renumbering of tables	Modify	Technical updates	Yes
Changes to Burden	• Addition of language to capture revisions in the 30-day package	Add/Modify	Technical update	No
Information Collection Forms				
Throughout	• Revisions to incorporate references to the final guidance and to align with definitions and other terms used in the final guidance	Modify	Technical updates	No
Small Biotech Exception				
Section A	• Addition of text to the instruction for Question 2a to clarify that the question relates to the Submitting Manufacturer, and not the qualifying single source drug • Addition of the word "mailing" to the Address field for Question 2b • Revisions to instructions and Question 3 for qualifying single source drugs with distinct combination of active moieties/active ingredients	Add/Modify	Technical updates	No

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Section B	• Addition of the word "mailing" to the Address field for Questions 4a and 5b • Addition of the response fields for Labeler Code(s) to Questions 4a and 5b • Revisions to instructions to clarify that Question 5 collects information about the members of that entity's controlled group (if any) as of December 31, 2021 that had a Coverage Gap Discount Program Agreement in effect on December 31, 2021	Add/Modify	Technical updates	No
Section C	• Addition of the word "mailing" to the Address field for Question 6b • Revisions to instructions for Question 6d to clarify the response is intended if the Submitting Manufacturer held no other New Drug Application(s) and/or Biologic License Application(s) as of December 31, 2021, other than those for the qualifying single source drug for which the Submitting Manufacturer seeks the Small Biotech Exception	Add/Modify	Technical update	No
Biosimilar Delay				
Section 1	• Addition of the word "mailing" to the Address field for Question 1 • Addition of an (s) to Active Ingredient in Question 2 to allow for a response with multiple Active Ingredients • Revisions to the "Reference Product" field in Question 4 to clarify the information requested in the data field	Add/Modify	Technical updates	No
Section 3	• Revisions to reflect that one manufacturing schedule would have been submitted to the Food and Drug Administration during its review of the Biosimilar's application for licensure • Revisions to the citations provided in Questions 11, 12, and 13	Modify	Technical updates	No

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Identification and Selection of Renegotiation-Eligible Drugs				
Throughout	• Revisions to incorporate references to the final guidance • Revisions to incorporate revisions to defined terms from Appendix A of the final guidance • Revisions to incorporate instructions for questions also included in the forthcoming Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (CMS-10844, OMB 0938-1452) to provide for consistency between the two ICRs where applicable, for example, for describing the reporting time period for prior Federal financial support (Section 3) and for reporting of units for manufacturer U.S. commercial average net unit price (Section 5)	Modify	Technical updates	No
Submission Method	• Revisions to clarify instructions for submission of responses	Modify	Technical updates	No
Additional Instructions	• Revisions to clarify instructions regarding the 11-digit National Drug Codes (NDC-11s) for which a Primary Manufacturer should report data in response to the ICR Form	Modify	Technical update	No
Instructions for Reporting Monetary Amounts	• Revisions to instruction for converting another currency to United States dollars to clarify which exchange rate to use • Revisions to instructions for inflation adjustments to specify the consumer price index for all urban consumers	Modify	Technical updates	No
Sections 1, 3, and 4	• Revisions to Questions 3, 6 and 7 to separate data fields for reporting of inflation adjusted values • Revisions to Sections 1, 3 and 4 with respect to the periods of time for which data should be reported	Modify	Revisions to align with the final guidance and technical updates	No
Section 1	• Revisions to Section 1 to clarify instructions for reporting research and development (R&D) costs and recoupment data • Revisions to instructions to clarify that prior Federal financial support and costs associated with applying for and receiving foreign approvals may not be included in Section 3	Modify	Revisions to align with the final guidance and technical updates	No

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Section 3	• Revisions to Section 3 instructions to align with Section 1 regarding the reporting period for prior Federal financial support	Modify	Revisions to align with the final guidance and technical updates	No
Section 4	• Revisions to Section 4 to clarify the instructions and examples of information to be submitted • Removal of request to identify the composition of matter patent in Question 9a	Modify	Technical updates	No
Section 5	• Addition of instruction regarding units to be submitted for the data elements included • Revision to instruction to clarify the NDC-11s that a Primary Manufacturer should include in response to Section 5	Modify	Technical updates	No
Section 6	• Revision to align the starting date and ending date of the data that may be submitted in Questions 14 and 15 with sections 130.1.3 and 130.1.4 of the final guidance • Revisions to add the option to submit visual attachments to Questions 14 and 15 and to include citations in Question 15	Modify	Revisions to align with the final guidance and technical updates	No