Small Biotech Exception and Biosimilar Delay Information Collection Request (ICR) for Initial Price Applicability Year 2027:

Crosswalk of Changes Between 60-Day and 30-Day 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 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereinafter, the "final guidance"), in lieu of the draft version of the guidance	Modify	Technical Update	No
Justification	• Revisions to clarify ICR submission window • For the explanation of the Biosimilar Delay, revisions to clarify that the Biosimilar will be licensed and bona fide marketed within two years of the statutorily-defined selected drug publication date for initial price applicability year 2027	Modify	Technical Updates consistent with the final guidance	No
Federal Register	• Addition of language to capture a summary of the 60-day timely public comments received	Add/Modify	Technical Update	No

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Burden Estimates	• Moved wage information for respondents' occupations to one table and deleted wage and fringe and benefit columns from each individual table • Revised text explanation of hours related to Table 3 to be consistent with the table	Modify	Technical Updates	No
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Throughout	• Revisions to incorporate reference to the final guidance, in lieu of the draft guidance	Modify	Technical Update	No
Small Biotech Exception				
Instructions	• Revisions to clarify submission window	Modify	Technical Update consistent with the final guidance	No
Instructions and Question 2a	• Revisions to clarify the instructions and question related to whether the Submitting Manufacturer holding the New Drug Application(s) (NDA) or Biologics License Applications(s) (BLA) for the qualifying single source drug was acquired by another entity after 2021	Modify	Technical Update consistent with the final guidance	No
Biosimilar Delay				

Instructions	• Revisions to clarify submission window	Modify	Technical Update consistent with the final guidance	No
Location of Edits	**Summary of Changes (Included for 30-day Comment Period)**	**Type of Change**	**Explanation of Changes**	**Burden Change (Yes/No)**
Question 3	• Revisions to clarify instructions that if a Biosimilar Manufacturer has not submitted an application in response to Question 3, respondents will be able to indicate that Question 3 is not applicable	Modify	Technical Update	No
Questions 8 and 10	• Revisions to the instructions to regarding the CMS determination about the high likelihood that the Biosimilar will be bona fide marketed before February 1, 2027	Modify	Technical Update consistent with the final guidance	No