Small Biotech and Biosimilar Delay ICR Crosswalk of Changes Between IPAY 2026 Final[1] and IPAY 2027 60-Day Documents

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No/Not Applicable (N/A) [2])
Supporting Statement – Part A				
Introduction	• Addition of an Introduction to clarify that OMB 0938-1443 will include the Biosimilar Delay Information Collection Request Form as well for initial price applicability year 2027 • Revisions to the applicability date of this statement to initial price applicability year 2027	Add	Administrative decision to streamline review of PRA renewals of this notice Technical Update	N/A
Throughout (Small Biotech)	• Addition of language to capture the statutory requirement regarding limitation of the small biotech exception to an acquiring entity that is not a specified manufacturer as of 12/31/21, effective in the case of an acquisition before 2025, effective January 1, 2025 • Reordering of questions to accommodate questions related to the limitation	Add/Modify	Additions to address statutory requirement at section 1192(d)(2)(B)(ii) of the Social Security Act (the Act)	N/A

[1] The IPAY 2027 Biosimilar Delay ICR Form was included as Appendix B in the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, available at https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[2] N/A is listed under burden change when the revision is not a substantive revision to the information collection.

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No/Not Applicable (N/A) [2])
Throughout (Biosimilar Delay)	• Addition of language to capture the inclusion of an information collection request from a Biosimilar Manufacturer for CMS' consideration to delay of a negotiation-eligible drug that includes the reference product for the Biosimilar drug on the selected drug list for initial price applicability year 2027	Add	Administrative decision to streamline review of PRA renewals of this notice	Yes
Justification, Information Collected and Federal Register/Outside Collection	• Revisions to information requested from a Submitting Manufacturer to align with Information Collection Form revisions to Questions 2 and 3	Modify	Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	N/A
Justification, Burden Estimates	• Revisions to wages to incorporate May 2023 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates • Revisions to hours to include time for technical assistance in form(s) completion	Modify	Technical Update	N/A
Justification, Cost to Federal Government (Small Biotech)	• Revisions to hourly wages to incorporate the 2024 general pay schedule • Revisions to hourly estimates of a GS-13 Federal employee providing technical direction to a contractor to maintain the existing information technology system for this tool that was built for the initial year of approval of this OMB form	Modify	Technical Update	N/A

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Information Collection Request (ICR) Forms				
Introduction	• Addition that OMB 0938-1443 will include the Biosimilar Delay Information Collection Request Form as well for initial price applicability year 2027	Add	Administrative decision to streamline review of PRA renewals of this notice	N/A
ICR Form – Small Biotech				
Throughout	• Revisions to the applicability date of this statement to initial price applicability year 2027	Modify	Technical Update	No
Instructions	• Addition of language to capture the statutory requirement regarding limitation of the small biotech exception to an acquiring entity that is not a specified manufacturer as of 12/31/21, effective in the case of an acquisition before 2025, effective January 1, 2025 • Revisions to information requested from a Submitting Manufacturer to align with Information Collection Form revisions to Question 3 (e.g., 11-digit National Drug Codes)	Add	Additions to address statutory requirement at section 1192(d)(2)(B)(ii) of the Social Security Act (the Act) Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes

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Question 2a and b	• Addition of new Question 2a determine if the Submitting Manufacturer was acquired after 2021 to align with the statutory limitation at section 1192(d)(2)(B)(ii) of the Act • If so, addition of Question 2b to identify the acquiring entity		Additions to address statutory requirement at section 1192(d)(2)(B)(ii) of the Social Security Act (the Act)	Yes
Previous Question 3	• Removal of previous Question 3 (NDC-11s)	Modify	Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes
Reordering of remaining questions	• Reordering of Questions 3-4 to accommodate revisions to previous and new Questions 2 and 3	Modify	Technical Update	No
Certification	• Addition of signatory identifying information to align with the Biosimilar Delay	Add	Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	No
ICR Form – Biosimilar Delay				
Introduction	• Revisions to introductory language to include the information collection form for a biosimilar delay submission for initial price applicability year 2027 for OMB PRA approval	Modify	Administrative decision to streamline review of PRA renewals of this notice	N/A
Throughout	• Revisions to the applicability date of this statement to initial price applicability year 2027	Modify	Technical Update	No
Instructions	• Addition of instructions regarding HPMS user access and deadline for initial price applicability year 2027	Modify	Technical Update to use the HPMS tool for initial price applicability year 2027 submissions	No

Location of Edits	Summary of Changes (Included for 60-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No/Not Applicable (N/A) [2])
Questions, throughout	• Revisions to format table options and documentation submission mechanism for HPMS in lieu of a fillable PDF and Box file uploads	Modify	Technical Update	No
Question 1	• Removal of "Entity Type"	Modify	Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes
Question 2	• Revised "Product Name" to "Biosimilar Name"	Modify	Technical Update	No
Question 3	• Revisions to "Approval Date" column to allow a respondent to specify the date for each type of "Application Status" in the column prior	Modify	Technical Update	Yes
Question 4	• Revised "Product Name" to "Reference Product" • Removal of "Active Ingredient" and "NDC-9s"	Modify	Technical Update Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes
Question 5	• Removal of "Entity Type", "EIN", "Address", "P number" and "Labeler Code"	Modify	Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes
Question 9	• Instructions added to clarify Option C or D selections	Modify	Policy changes based on lessons learned from initial price applicability year 2026 submissions	No
Question 11	• Revisions to the instructions when Option C or D is selected	Modify	Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	No

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Questions 12-14	• Addition of a request for explanation when no supporting documentation is available	Modify	Policy changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes