Drug Price Negotiation Process ICR Crosswalk of Changes Between 60-Day Notice and 30-Day Notice

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes	Impact to Burden
Supporting Statement (Background and Justification)	• Modified the "Background" and "Justification" headers to "A. Background" and "B. Justification" for organization	Modify	Changes due to internal or administrative review	None
Supporting Statement (throughout) and ICR Form (throughout)	• Revised language around the 10 high expenditure, single source drugs covered by Medicare Part D that will be selected for negotiation to align with the revised guidance[1]	Modify/Add	Changes due to internal or administrative review, including guidance review	None
Supporting Statement (Background) and Drug Price Negotiation Process ICR Form (hereinafter, "ICR Form," (Introduction))	• Revised language around when the negotiation period starts for initial price applicability year 2026	Modify	Changes due to internal or administrative review, including guidance review	None
Supporting Statement (throughout) and ICR Form (throughout)	• Removed references to the initial guidance and "Negotiation Data Elements" Information Collection Request. Replaced with references to the revised guidance.	Modify/Add	Changes due to internal or administrative review, including guidance review	None
Supporting Statement (Background) and ICR Form (Introduction)	• Revised language around the goal of the offer and counteroffer process to align with the revised guidance	Modify/Add	Changes due to internal or administrative review, including guidance review	None

[1] https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes	Impact to Burden
Supporting Statement (Background) and ICR Form (Introduction)	• Revised language detailing the negotiation process after the written initial offer to align with the revised guidance	Modify/Add	Changes due to internal or administrative review, including guidance review	None
Supporting Statement (Background)	• Added information on what the Counteroffer Form will collect	Add	Changes due to internal or administrative review	None
Supporting Statement (Need and Legal Basis)	• Clarified that the written initial offer for the MFP is for a selected drug	Add	Changes due to internal or administrative review	None
Supporting Statement (Information Users)	• Revised language to state that CMS will use information submitted by Primary Manufacturers and other interested parties to seek to reach agreement on an MFP for a selected drug	Add	Changes due to internal or administrative review	None
Supporting Statement (Use of Information Technology)	• Added language saying that the Drug Price Negotiation Process ICR Form will be available and must be submitted in the CMS Health Plan Management System (HPMS)	Add	Changes due to internal or administrative review	None
Supporting Statement (throughout) and ICR Form (throughout)	• Revisions to refer to "the CMS HPMS" when discussing the system where Primary Manufacturers will submit information, in alignment with the revised guidance	Modify	Changes due to internal or administrative review, including guidance review	None

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes	Impact to Burden
Supporting Statement (Small Business)	• Added a citation to the statute when discussing the small biotech exception	Add	Changes due to internal or administrative review	None
Supporting Statement (Special Circumstances)	• Revised language around how proprietary information would be protected from disclosure to align with the revised guidance	Modify	Changes due to internal or administrative review, including guidance review	None
Supporting Statement (Footnote 3)	• Updated footnote language regarding the Small Biotech Exception ICR to reflect that it was approved	Modify	Changes due to internal or administrative review	None
Supporting Statement (Footnote 4)	• Added a footnote to a DOJ webpage around data disclosure and FOIA	Add	Changes due to internal or administrative review	None
Supporting Statement (Federal Register/Outside Consultation)	• Replaced placeholders with the date and Federal Register citation for the 60-day package	Add	Technical update	None
Supporting Statement (Federal Register/Outside Consultation)	• Added a summary of the comments received during the 60-day comment period	Add	Technical update	None
Supporting Statement (Payments/Gifts to Respondents)	• Removed language around excise tax liability	Modify	Changes due to internal or administrative review	None
Supporting Statement (Confidentiality)	• Updated confidentiality language to reflect policy in the revised guidance	Modify	Changes due to internal or administrative review, including guidance review	None
Supporting Statement (Footnote 5)	• Updated footnote links to DOJ documents on FOIA Exemptions	Modify	Changes due to internal or administrative review	None

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes	Impact to Burden
Supporting Statement (Burden Estimate)	• Clarified when a Primary Manufacturer must submit the Counteroffer Form	Modify	Changes due to internal or administrative review	None
Supporting Statement (Burden Estimate)	• Updated the time and cost burden estimate for a Primary Manufacturer to develop and submit a counteroffer • Updated the source of the wage estimates used for burden calculations; industry-specific wage estimates were used when available • Added statutory references for the initial offer and counteroffer process • Updated the list of roles accounted for the burden estimate to prepare and submit the Counteroffer Form	Modify	Changes due to internal or administrative review; Changes in response to comments	None
Supporting Statement (Changes to Burden)	• Added language saying that the burden estimate for Primary Manufacturers developing and submitting a counteroffer was modified • Updated the source of the wage estimates used for burden calculations; industry-specific wage estimates were used when available	Add	Changes due to internal or administrative review; Changes in response to comments	None

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes	Impact to Burden
ICR Form (Instructions)	• Revised language on what the counteroffer justification should entail to align with the revised guidance • Added language on possible sources for 1194(e) data, including the Primary Manufacturer's October 2, 2023 data submission, other interest parties' October 2, 2023 data submission, and information otherwise available and considered by CMS	Modify/Add	Changes due to internal or administrative review, including guidance review	None
ICR Form (Instructions)	• Added counteroffer justification instructions on the revised word limit and new fields to upload supporting information and include citations • Added instructions on how Primary Manufacturers should input the counteroffer price as a 30-day equivalent supply of the selected drug • Added language on how CMS will review information submitted for use of cost-effectiveness measures	Add	Changes in response to comments	None
ICR Form (Instructions)	• Added instructions on how Primary Manufacturers should use new fields added to the form	Add	Changes due to internal or administrative review	None

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes	Impact to Burden
	that indicate if information submitted uses cost-effectiveness measures			
ICR Form (Form, Introduction)	• Revisions for clarity, an updated statutory citation, and to align with the revised guidance	Modify	Changes due to internal or administrative review	None
ICR Form (Question 2)	• Clarified how CMS will interpret the single counteroffer for the MFP submitted by Primary Manufacturers • Added that CMS will provide information on computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug in advance of the initial offer, which Primary Manufacturers can use to see how a single MFP would apply to different dosage forms and strengths • Streamlined language for clarity and to align with the revised guidance	Add	Changes due to internal or administrative review, changes in response to comments	None
ICR Form (Question 3)	• Updated the word limit for the counteroffer justification • Added a field where Primary Manufacturers may upload information to support the counteroffer justification	Add	Changes in response to comments, changes due to internal or administrative review	Moderate, accounted for in increased burden estimate. Respondents will upload supporting documents and citations in addition to their justification. Respondents

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes	Impact to Burden
	• Added a field for citations • Added questions to determine if any information submitted uses cost-effectiveness measures • Streamlined language for clarity and to align with the revised guidance			will review information submitted for use of cost-effectiveness measures and attest accordingly
ICR Form (PRA Disclosure Statement)	• Updated the burden estimate to develop and submit a counteroffer		Changes in response to comments	None

[i] References to section and question numbers reflect the lettering and numbering in the revised 30-day notice.