Negotiation Data Elements and Drug Price Negotiation Process Information Collection Request (ICR) for Initial Price Applicability Year 2027
Crosswalk of Changes Between the 60-Day and 30-Day Documents[i]

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Supporting Statement				
Throughout	• Revised references about the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereinafter the "draft guidance") to the final version of this guidance ("final guidance")	Modify	Technical Update	No
Background	• Revised summary of the Counteroffer Process to reflect revisions made to the negotiation process in the final guidance	Modify	Revisions made in response to comments received from the ICR 60-Day Comment Period and to align with final guidance	No
Burden Estimates	• Revised the burden estimate for Primary Manufacturers to submit section 1194(e) data for selected drugs	Modify	Revisions made in response to comments received from the ICR 60-Day Comment Period	Yes
Information Collection Request (ICR) Forms				
Throughout	• Revised references of the draft guidance to the final guidance • Revisions to reference "potential" therapeutic alternatives	Modify	Technical Update and Revisions to align with final guidance	No
Instructions	• Added instruction for reporting the geographic area for data on U.S. Commercial markets, Medicare markets, and Medicaid markets • Revised instructions related to identification of proprietary information • Clarified instructions on number of submission files for visual representations • Revised instruction related to inflation adjustment	Add	Revisions made in response to comments received from the ICR 60-Day Comment Period and to align with final guidance	No
ICR Form – Negotiation Data Elements				

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Definitions, throughout	• Revised or added the following terms to correspond to revisions of these terms included in Appendix A of the final guidance: o Drug Sample o United States o Labeler Code o Direct basic, pre-clinical research costs o Direct post-IND costs o Direct research expenses and direct post-IND costs o All other R&D direct costs, o Prior Federal financial support o Patents, Exclusivities, and Approvals o Manufacturer net Medicare Part D average unit price o Manufacturer net Medicare Part D average unit price – best o Therapeutic Advance o Therapeutic Alternative o Outcomes	Add/Modify	Revisions made to align with final guidance	No
Section A	• Added an instruction regarding the use of 'Discontinued' within the table to clarify what date should be submitted if a drug is discontinued	Add	Revisions made in response to comments received from the ICR 60-Day Comment Period	No
Section C	• Revised instructions in Question 2c to reduce duplication with Question 2b and increased the character count for Question 2c • Revised Question 4 to separate out Question 4b from 4c, consistent with Questions 2 and 3 • Revised instructions for Question 4a to align with definitional updates for Question 4 • Revised instructions to Questions 6a and 6b regarding inflation adjustment	Modify	Revisions made in response to comments received from the ICR 60-Day Comment Period	Yes
Section D	• Revised the reporting time period for the average unit costs during the 12-month period	Modify	Revisions made in response to comments received from the ICR 60-	Yes

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
	• Revised the term "third parties" to "third-party vendors" • Revised the decimal places for Question 7 from two three decimal places consistent with the instructions • Revised the National Council for Prescription Drug Programs **(**NCPDP) unit column to be consistent with the formatting of other questions in Sections A-G requesting NCPDP units		Day Comment Period and to align with final guidance	
Section E	• Revised instructions for Questions 9 and 10 regarding inflation adjustment	Modify	Revisions made in response to comments received from the ICR 60-Day Comment Period	Yes
Section F	• Separated the tables for Question 12 into tables for Question 12A (patents) and Question 12B (patent applications) • Modified table columns; for example, modified drop down options in "Patent Type" column and deleted columns for "drug substance patent," "drug product patent," and "method-of-use patent;" added column for explanation of patent and made attachment of patent application optional for Question 12A • Deleted Question 13 and renumbered Questions 14 and 15 as 13 and 14, respectively	Modify/Add/Remove	Revisions made in response to comments received from the ICR 60-Day Comment Period and to align with final guidance	Yes
Section G	• Revised the reporting period for Question 17 from five years to three years • Removed duplicate request for explanation of missing reporting data to Questions 19 and 21 • Revised the instructions for the reporting period in Question 15 • Revised the reporting period for Question 23 to align with Section A and Question 15 • Added a general instruction on reporting total unit volume and revised the instructions for reporting units in Questions 23 and 25	Modify/Add	Revisions made in response to comments received from the ICR 60-Day Comment Period and to align with final guidance	Yes

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
	• Added a column to Question 23 titled Total Unit Volume for U.S. Commercial Average Net Unit Price • Added instructions to question 23 on reporting Manufacturer U.S. Commercial Average Net Unit Price and Total Unit Volume for U.S. Commercial Average Net Unit Price - Best • Added an instruction to Question 25 for reporting Total Unit Volume for Net Medicare Part D Average Unit Price – Best • Added an instruction to Question 26 titled Explanation of Information Reported in Response to Question 25: Manufacturer net Medicare Part D price • Revised the reporting period for Question 26 to align with Section A and Question 16 • Added a column to Question 26 titled "Total Unit Volume for Average Net Unit Price to Part D Plan Sponsors – Best"			
Question 27	• Increased the character limit • Technical edits to question • Revised instructions and references to "proprietary information"	Modify	Revisions made in response to comments received from the ICR 60-Day Comment Period	No
Section I	• Revised instructions to clarify that respondents are not required to submit personally identifiable information (PII) or protected health information (PHI) • Added a reference to section 504 of the Rehabilitation Act in the General Instructions for Section I as it relates to CMS' review of cost effectiveness measures • Clarified the application of the general instructions to Section I • Removed previously numbered Question 30 regarding off-label use from the manufacturer-focused questions, and removed cross-references to	Modify/Add/Remove	Revisions made in response to comments received from the ICR 60-Day Comment Period	No

Location of Edits	Summary of Changes (Included for 30-day Comment Period)	Type of Change	Explanation of Changes	Burden Change (Yes/No)
	previously-numbered Question 30 in Section I and off-label use within Questions 29-35 • Added request in Question 44c for guidelines supporting off-label use, if applicable • Renumbered questions in Section I • CMS provided additional clarification in the instructions for Questions 29-35 to clarify that dossier submission is optional • Added more examples of factors that could impact the choice to take a medication, or not, and added "mail- order pharmacy" access to Questions 38a2 and 39b2 • Added a prompt to Questions 38a3 and 39b3 to gather information on whether taking the selected drug has impacted the patient's emotional or mental well-being • To Questions 44a and 44b, added examples of treatment goals (remission, symptom management, or quality of life improvement, or cure); and examples of types of outcomes (clinical, functional, or patient-reported) • Added clarifying instruction related to off-label use in Questions 44c and 50a • Revised directions for clarity to Question 52c			
Question 62	• Increased the character limit • Technical edits to question • Revised references to "proprietary information"	Modify	Revisions made in response to comments received from the ICR 60-Day Comment Period and to align with final guidance	No
PRA Disclosure Statement	• Revised the burden estimate to match revisions to the Supporting Statement • Revised text to align with updated standard language for PRA Disclosure Statements	Modify	Revisions made in response to comments received from the ICR 60-Day Comment Period	Yes
ICR Form – Drug Price Negotiation Process				
Throughout	• Revised title of form from "Counteroffer ICR Form" to "Statutory Written Counteroffer ICR Form"	Modify	Revisions made to align with 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)
	• Revised the phrase “counteroffer price” to “counteroffer proposal for the MFP” • Revised summary of the Counteroffer Process to align with the negotiation process as described in the final guidance			
Instructions	• Revised instructions on uploaded visual representations of information (including tables, charts, and/or graphs) to align with similar instructions in Section I of the Negotiation Data Elements form	Modify	Technical Update	No
PRA Disclosure Statement	• Revised text to align with updated standard language for PRA Disclosure Statements	Modify	Technical Update	Yes

[i] Question numbering matches 30-day document.