

Drug Price Negotiation 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 and 30-Day Proposed 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				
Throughout	<ul style="list-style-type: none"> 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”) 	Modify	Technical updates related to updating program guidance references	No
Federal Register/Outside Consultation	<ul style="list-style-type: none"> Revisions to summarize revisions incorporated in response to public feedback on the 60-day version and to explain that CMS will review and provide appropriate revisions based on any 30-day comments in the final version 	Modify	Technical updates	No
Burden Estimates	<ul style="list-style-type: none"> Removal of Table 8 because the information is duplicative of Tables 6 and 7, and renumbering of tables thereafter 	Remove/Modify	Technical updates	No
Changes to Burden	<ul style="list-style-type: none"> Revisions to summarize revisions incorporated in 30-day version, which do not alter burden estimate 	Modify	Technical updates	No
Information Collection Request (ICR) Forms				
Throughout	<ul style="list-style-type: none"> Revisions to incorporate references to the final guidance Revisions to definitions throughout, as applicable, to align with the final guidance 	Add/Modify	Revisions and additions to align with final guidance; Technical updates	No
ICR Form – Negotiation Data Elements				
Submission Method	<ul style="list-style-type: none"> Removal of instructions regarding email registration access for Section I 	Remove	Revisions to align with technical updates to the CMS Health Plan Management System (CMS HPMS)	No
Section A	<ul style="list-style-type: none"> Revision of instruction regarding the selection of inner and outer packages Revision to the pincite for the date of discontinuation (in the footnote) Revisions of data fields for 11-digit National Drug Codes (NDC-11s) marked as “discontinued,” a “sample package,” an “inner 	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)
	package,” an “outer package,” and a “private label,” from “Text” to “Yes/No” to align with the options to be available in the CMS HPMS			
Section C	<ul style="list-style-type: none"> Revisions to instructions throughout Section C with respect to the periods of time for which data should be reported for drugs selected for negotiation and for drugs selected for renegotiation 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 E 	Modify	Revisions to align with final guidance; Technical updates	No
Section E	<ul style="list-style-type: none"> Revisions to instructions with respect to the periods of time for which data should be reported Revisions to Questions 6 and 7 to add separate data fields for reporting of inflation adjusted values 	Modify	Revisions to align with final guidance; Technical updates	No
Section F	<ul style="list-style-type: none"> Revisions to instructions (both general instructions and specific instructions for each question) with respect to the periods of time for which data should be reported for the drugs selected for renegotiation Removal of column “Is Patented Product Available to Purchase in the Applicable Market?” in Question 9A to align with the Negotiation Program Drug Selection Information Collection Request Revision of title for the “Patent Explanation” data field in Questions 9A and 9B 	Modify/ Remove	Revisions to align with final guidance; Technical updates	No
Section G	<ul style="list-style-type: none"> Addition of Questions 14 and 15 for the reporting of Average Sales Price (ASP) to align with the final guidance, and renumbering of questions thereafter From the information specified that a Primary Manufacturer should address, when applicable, in the Primary Manufacturer’s explanation of “Manufacturer net Medicare Part D price” in response to Question 25, CMS removed the allocation of financial assistance to a patient from the list because CMS understands that due to longstanding fraud and abuse law these arrangements are unlikely to exist in Medicare Part D 	Modify/ Remove	Revisions to align with final guidance; 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)
	<ul style="list-style-type: none"> Revised the instructions for Question 23 to clarify that the information reported address both “Manufacturer Net Medicare Part D Average Unit Price” and the “Manufacturer Net Medicare Part D Average Unit Price – best” to align with the instructions for Question 23 Removal of the instruction to leave the data fields listed below (by question number) blank when entering an NDC with a unit volume of “0” to align with the CMS HPMS: <ul style="list-style-type: none"> Question 12: Wholesale Acquisition Cost Question 14: Average Sales Price Question 16: Medicaid Best price Question 18: Federal Supply Schedule Price Question 20: Big Four Price Question 22: Manufacturer U.S. Commercial Average Unit Net Price, Manufacturer U.S. Commercial Average Unit Net Price - Net of Patient Assistance Programs, Manufacturer U.S. Commercial Average Unit Net Price – Best Question 24: Manufacturer Net Medicare Part D Average Unit Price, Manufacturer Net Medicare Part D Average Unit Price – Best, Manufacturer Net Medicare Part D Average Unit Price Amount Paid 			
Section H	<ul style="list-style-type: none"> Revision of pincite to section 1197(c) of the Act by removing reference to (7) 	Modify	Technical update	No
Question 26	<ul style="list-style-type: none"> Revisions to instructions and data fields to clarify the scope of information requested and the formatting required for the response 	Modify	Technical updates	No
Section I	<ul style="list-style-type: none"> Bolded and changed the font color of the instruction that responses to individual questions should not be duplicated Revision to add “potential” to all references to therapeutic alternative(s) Revisions to reduce the character limits for questions that request a list (e.g., Question 28a3) or a list and a brief explanation (e.g., Question 38) where CMS has observed responses may be duplicative across these questions which 	Modify	Revisions to align with final guidance; 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)
	<p>may increase respondents' response burden and CMS' internal review time</p> <ul style="list-style-type: none"> • Revision to Questions 34, 42c, and 47 to add an explanation of the potential therapeutic alternative(s) and indication(s) included in response to Question 34, 42c, and 47, respectively • Revision to Question 37 to include a Question 37a and a Question 37b • Revisions to clarify instructions in Question 39 regarding the submission of an outline with the drug dossier • For questions with a Yes/No response in Section I, addition of directions to clarify the next question the respondent should review based on whether the respondent selected Yes or No to the preceding applicable question • Revisions of the character limits for the following questions: Questions 34, 35b, 38a, 38b, 41b, 42a through 42g, 47, and 48b • Addition of a character limit for Question 41b • Revisions to the instructions for Question 55 • Revisions throughout to clarify references to citations in Question 56 • Revisions to Question 56 to remove the manual entry option and require a PDF upload only to submit a list of citations to align with the CMS HPMS • Revisions to Question 56 in the data field for the Pub Med ID and/or DOI to clarify the information requested 			
Question 57	<ul style="list-style-type: none"> • Revisions to instructions and data fields to clarify the scope of information requested and the formatting required for the response 	Modify	Technical updates	No

*Question numbering matches 30-day document.