

### Negotiation Data Elements and Drug Price Negotiation Process ICR Crosswalk of Changes Between IPAY 2026 Final 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) <sup>1</sup> )
Supporting Statement				
Throughout	<ul style="list-style-type: none"> <li>Revisions to the applicability date of this statement to initial price applicability year 2027</li> </ul>	Modify	Technical Update	No
Introduction	<ul style="list-style-type: none"> <li>Addition of an Introduction to clarify that OMB 0938-1452 will include Negotiation Data Elements ICR Form for initial price applicability year 2027, in addition to revisions to the Drug Price Negotiation Process ICR Form</li> </ul>	Add	Administrative decision	N/A
Use of Information Technology	<ul style="list-style-type: none"> <li>Revisions to reflect that CMS has developed an automated tool within the CMS Health Plan Management System (CMS HPMS) and that the forms must be submitted through CMS HPMS</li> </ul>	Modify	Technical Update	Yes
Federal Register/Outside Consultation	<ul style="list-style-type: none"> <li>Revisions to the 60-day notice publication date and that CMS will review and address appropriate revisions based on comments</li> <li>Addition of consultation with Department of Veterans Affairs and the Food and Drug Administration</li> </ul>	Modify	Technical Update	No
Payments/Gifts to Respondents	<ul style="list-style-type: none"> <li>Revisions to clarify that the Primary Manufacturer's counteroffer submission is relevant to CMS actions for the remainder of the negotiation process, not only for the final offer</li> </ul>	Modify	Technical Update	No
Justification, Burden Estimates	<ul style="list-style-type: none"> <li>Revisions to wages to incorporate May 2023 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage</li> </ul>	Modify	Technical Update	Yes

<sup>1</sup> N/A is listed under burden change when the revision is not a substantive revision to the information collection.

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	<p>Estimates and May 2023 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry, when available</p> <ul style="list-style-type: none"> <li>• Revision from use of mean hourly wages to median hourly wages</li> <li>• Revisions to total burden for Primary Manufacturers to reflect an increased number of selected drugs in initial price applicability year 2027</li> <li>• Revisions to the number of respondents for public feedback based on initial price applicability year 2026 experience</li> </ul>			
Justification, Cost to Federal Government	<ul style="list-style-type: none"> <li>• Revisions to hourly wages to incorporate the 2024 general pay schedule</li> <li>• Revisions to CMS staff burden for Negotiation Data Elements to allocate burden hours</li> <li>• Revisions to CMS GS-13 through GS-15 staff salaries to reflect step 1 salaries instead of step 4 in the Negotiation Data Elements burden estimate</li> <li>• Revises to cost to government to reflect modifications to the pre-existing CMS HPMS module to collect this information</li> <li>• Revisions to total burden for CMS staff to reflect an increased number of selected drugs in initial price applicability year 2027</li> </ul>	Modify	Technical Update	Yes
Information Collection Request (ICR) Forms				
Throughout	<ul style="list-style-type: none"> <li>• Revisions to the applicability date of this statement to initial price applicability year 2027</li> </ul>	Modify	Technical Update	No

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Instructions, General Instructions	<ul style="list-style-type: none"> <li>• Changed word counts to character counts. Revised character counts to reflect estimated amount of information required to provide a sufficient answer</li> <li>• Overview of Primary Manufacturer requirements to provide updated information from Sections A through G of the Negotiation Data Elements form to CMS</li> <li>• Addition of instructions regarding identification of information submitted that may be exempt from disclosure under FOIA</li> </ul>	Add/Modify	Changes based on lessons learned from review of initial price applicability year 2026 submissions	No
ICR Form – Negotiation Data Elements				
Definitions, throughout	<ul style="list-style-type: none"> <li>o Addition of the following defined terms: <ul style="list-style-type: none"> <li>o Drug sample (Section A)</li> <li>o Labeler code (Section A)</li> <li>o Private label distributor (Section A)</li> <li>o Total AMP units per package (Section A)</li> <li>o Total NCPDP units per package (Section A)</li> <li>o Transfer prices (Section D)</li> <li>o Manufacturer net Medicare Part D price (Section G)</li> <li>o Therapeutic Advance (Section I)</li> <li>o Indication (Section I)</li> <li>o Off-label Use (Section I)</li> </ul> </li> <li>o Revision of the following defined terms: <ul style="list-style-type: none"> <li>o Costs of Failed or Abandoned Products Related to the Selected Drug (Section C)</li> <li>o Direct Costs of Other R&amp;D for the Selected Drug (Section C)</li> </ul> </li> </ul>	Add/Modify	Definitional changes correspond to 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 Initial Price Applicability Years 2026 and 2027	Yes

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	<ul style="list-style-type: none"> <li>o Global and U.S. Total Lifetime Net Revenue for the Selected Drug (Section C)</li> <li>o Current unit costs of production and distribution of the selected drug (Section D)</li> <li>o Federal financial support for novel therapeutic discovery and development (Section E)</li> <li>o Patents (Section F)</li> <li>o Manufacturer U.S. commercial average net unit price (Section G)</li> <li>o Manufacturer U.S. commercial average net unit price—net of patient assistance program (Section G)</li> <li>o Manufacturer U.S. commercial average net unit price—best (Section G)</li> <li>o Therapeutic Alternative (Section I)</li> </ul>			
Section A	<ul style="list-style-type: none"> <li>• Added the following columns: Sample package, inner package, outer package, private label, NCPDP unit, total NCPDP units per package, AMP unit, total AMP units per package.</li> <li>• Removed the following columns: Dosage form, strength, unit.</li> </ul>	Add/Remove	Changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes
Section B	<ul style="list-style-type: none"> <li>• Split calendar quarter and year columns to allow for non-FAMP of calendar year 2021 or the first calendar year post entry to be reported.</li> <li>• Revised column heading from “total package unit volume” to “total NDC-11 package volume” to clarify CMS is asking for package volume (e.g., total number of bottles)</li> </ul>	Modify/Remove/Add	Changes based on lessons learned from review of initial price applicability year 2026 submissions.	Yes

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	<p>instead of unit volume (e.g., total number of tablets across bottles).</p> <ul style="list-style-type: none"> <li>Removed dosage form unit column.</li> <li>Moved the “Explanation of Non-FAMP Calculation” to a row-specific field and repurposed as “Explanation of why non-FAMP was not reported (if applicable).”</li> <li>Updated instructions to account for these changes.</li> <li>Added a new table with similar column headings to collect non-FAMP for calendar year 2024 per statute for IPAY 2027.</li> </ul>		<p>Added new information to collect because of additional statutory requirements for IPAY 2027.</p>	
Section C	<ul style="list-style-type: none"> <li>Separation of instructions and questions for each R&amp;D category such that the numerical response is a distinct question from the free response.</li> <li>Addition of new question asking manufacturers to indicate whether the selected drug was assigned to an FDA expedited program.</li> <li>Updated instructions to include accounting for non-monetary compensation</li> </ul>	Modify/Add	<p>Changes based on lessons learned from review of initial price applicability year 2026 submissions</p>	Yes
Section D	<ul style="list-style-type: none"> <li>Revised column heading of “indicate unit used” to “NCPDP unit”.</li> <li>Added “costs are not available” and “explanation of why costs are not available” columns to allow manufacturers to explain why costs are not available for prepopulated rows.</li> <li>Updated instructions to account for these above changes.</li> </ul>	Modify/Add	<p>Changes based on lessons learned from review of initial price applicability year 2026 submissions</p>	Yes

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Section E	<ul style="list-style-type: none"> <li>• Addition of instructions for reporting in-kind contributions and Cooperative Research and Development Agreements (CRADAs)</li> <li>• Addition of categories to Federal financial support to include CRADAs, in-kind contributions, and support for failed or abandoned indications for the selected drug.</li> <li>• Revision of instructions to clarify that Federal financial support should be listed from the highest support amount to lowest and to explain allocation methodology.</li> </ul>	Modify/Add	Changes based on lessons learned from review of initial price applicability year 2026 submissions	No
Section G	<ul style="list-style-type: none"> <li>• Revised period of data collection across all section G questions from most recent five years to three years ending December 31, 2024.</li> <li>• Revised column heading of “unit type (each, ML, GM)” to “NCPDP Unit (EA, ML, GM)” in questions 16, 20, 22, and 24.</li> <li>• Revised column heading of “unit type” to “AMP Unit (injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie)” in question 18.</li> <li>• Added a column to questions 16, 18, 20, 22, and 24 to allow the manufacturer to tell us why a particular price wasn’t reported (e.g., Explanation of why WAC was not reported (if applicable).</li> <li>• Revised “U.S. Commercial Average Net Unit Price” to “Manufacturer U.S. Commercial Average Net Unit Price” in questions 24 and 25.</li> </ul>	Modify/Add	Changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes

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	<ul style="list-style-type: none"> <li>Revised “U.S. commercial average net unit price– without patient assistance program” to “U.S. commercial average net unit price– net of patient assistance program” in questions 24-27.</li> <li>Added a new price to be reported in questions 26 and 27, “Manufacturer net Medicare Part D price.”</li> <li>Updated instructions to account for these above changes, to clarify which units should be reported in questions 20 and 22 for FSS price and Big Four price.</li> </ul>			
Question 28	<ul style="list-style-type: none"> <li>Addition of new question permitting Primary Manufacturers to identify information submitted that the respondent believes may be exempt under FOIA from disclosure</li> </ul>	Add	Changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes
Section I	<ul style="list-style-type: none"> <li>Revised instructions to reflect edits to questions in Section I.</li> <li>Added an optional request for demographic information for respondents that self-identify as a patient.</li> <li>Revisions to Section I questions to capture indication-specific information related to the selected drug and that selected drug’s therapeutic alternatives.</li> <li>Ordering of questions by potential respondent group types, but all questions may be answered by any respondent.</li> <li>Added list of FDA-approved indications for the selected drug for respondent reference.</li> <li>Added a request for a list of possible therapeutic alternative(s) for the selected drug.</li> </ul>	Modify	Changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes

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	<ul style="list-style-type: none"> <li>Added request for: evidence on clinical comparative effectiveness, prevalence of identified indications among the Medicare population, estimate of Medicare utilization of the selected drug for each indication, and estimates of health care resource utilization for the population using the selected drug and its therapeutic alternative(s).</li> <li>Added additional questions and revised previous questions on patient experience.</li> <li>Revised the question on unmet medical need.</li> <li>Added an optional request for manufacturers of selected drugs to submit dossiers to supplement their responses.</li> </ul>			
Question 64	<ul style="list-style-type: none"> <li>Addition of new question for respondents to Section I to identify information submitted that the respondent believes may be exempt under FOIA from disclosure</li> </ul>	Add	Changes based on lessons learned from review of initial price applicability year 2026 submissions	Yes
<b>ICR Form – Drug Price Negotiation Process</b>				
Throughout	<ul style="list-style-type: none"> <li>Revisions to the applicability date of this statement to initial price applicability year 2027</li> <li>Revision of word counts to character counts, and revision of character counts to reflect estimated amount of information required to provide a sufficient answer.</li> </ul>	Modify	Technical Update	No
Introduction	<ul style="list-style-type: none"> <li>Revisions to the summary of the counteroffer process to align with changes to draft guidance for initial price applicability year 2027</li> </ul>	Modify	Changes based on lessons learned from review of initial price applicability year 2026 submissions	No



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Introduction	<ul style="list-style-type: none"> <li>Revision to clarify definition of hybrid meetings</li> </ul>	Modify	Technical Update	No
Instructions	<ul style="list-style-type: none"> <li>Revisions to additional instructions to clarify respondents must indicate whether their submission includes cost-effectiveness methods</li> </ul>	Modify	Technical Update	No
Instructions, Question 2	<ul style="list-style-type: none"> <li>Revisions to specify a character count limit with an approximation of word count rather than a word-limit which may differ across word processing platforms</li> </ul>	Modify	Technical Update	No
Question 1	<ul style="list-style-type: none"> <li>Removed question 1 which asks for the name of the selected drug as this information will already be provided in CMS HPMS</li> </ul>	Remove	Technical Update	Yes