Negotiation Data Elements 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
Supporting Statement (throughout), Negotiation Data Elements ICR Form (hereinafter, "ICR Form" (throughout))	○ Revisions to terminology, for consistency with the revised program guidance issued concurrently with the 30-day comment period, including: ○ Section B: Clarified definition of non-FAMP and added definition of non-FAMP dosage form unit; ○ Section C, Question 2 definition: Clarified that the basic pre-clinical research period is determined in reference to each indication of the selected drug; ○ Section C, Question 3 definition: Broaden and clarified direct costs that should be included in post-IND costs; ○ Section C, Question 4 definition: Added definition of therapeutic class for purposes of reporting costs of failed or abandoned products	Modify / Add	Technical changes to be consistent with policy changes in response to comments and / or due to internal or administrative review, including guidance review

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	related to the selected drug. ○ Section C, Question 6 definition: Moved definitions of U.S. net revenue from Section G; added questions, instructions, and definitions for 6a and 6b. ○ Section F: Modified language in patent and exclusivity definitions and clarified types of FDA applications and approvals about which CMS is seeking information; ○ Section G: Clarified patient assistance programs to explain definition; removed certain definitions (e.g., 340B ceiling price, 340B prime vendor program price, covered entity, quarterly total U.S. unit volume, manufacturer average net unit price);		

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	and removed definition of gross revenue; ○ Section G: Added footnote to Big Four price definition; ○ Section G, Question 16: Changed reporting for WAC from NDC-9 to NDC-11; ○ Section G, Questions 24-25: Changed reporting for U.S. commercial average net unit price from NDC-9 to NDC-11; ○ Section H, Question 28: Added definition of therapeutic alternative; ○ Section H, Question 29: Added definitions of therapeutic alternative, outcomes, and patient-centered outcome; ○ Section H, Question 30: Added definition of specific populations and health equity; and ○ Section H, Question 31: Revised definition of unmet medical need.		

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
Supporting Statement (Justification)	• Moved location of information required by the Primary Manufacturer, added data factors CMS will consider in negotiating a maximum fair price and removed inapplicable examples, revised language to be consistent with guidance revisions • Updated language regarding submission methods to be consistent with guidance revisions	Modify / Add	Changes due to internal or administrative review, including guidance review
Supporting Statement (Federal Register)	• Revised language consistent with publishing a revised package for a 30-day public comment period and for added specificity	Add	Technical update
Supporting Statement (Cost to the Federal Government, Changes to Burden)	• Revised federal burden estimate to include the cost for modifications to the CMS HPMS system to include this ICR	Modify	Changes due to internal or administrative review
ICR Form (throughout)	• Revised section lettering and question numbering	Modify	Technical changes to be consistent with policy changes in response to comments

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
ICR Form (General Instructions)	• Revised formatting of sections and language to clarify submission method for the public	Modify	Technical update
ICR Form (General Instructions)	• Removed references to questions removed from this ICR in Section G	Modify	Policy change in response to comments
ICR Form (General Instructions)	• Modified language about calculating and reporting monetary values consistent with the ICR and generally accepted accounting principles	Modify	Technical changes to be consistent with guidance and external review
ICR Form (General Instructions)	• Revised instructions for Primary Manufacturers to not adjust any reported dollar amounts for inflation	Modify	Policy change in response to comments
ICR Form (Section A, Instructions and Questions)	• Revised instructions and questions to explain that CMS will pre-populate certain information for NDC-11s and ask Primary Manufacturers to supplement as applicable	Modify / Add	Technical changes to be consistent with guidance and external review
ICR Form (Section B, Instructions and Question)	• Revised instructions and table to include submission of dosage form unit	Modify	Policy change in response to comments
ICR Form (Section C, Instructions)	• Revised introductory language and instructions to match revisions made to questions	Modify	Policy change in response to comments

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
ICR Form (Section C, Question 1)	• Moved and modified definition, questions, and instructions for reporting of acquisition costs from Section G to new question 1	Modify/Revise	Policy change in response to comments
ICR Form (Section C, Questions 3 and5)	• Revised "Post-Investigational New Drug (IND) Application Costs" to include "Completed U.S. FDA-Required Post-marketing Trials" and "Other R&D Direct Costs" to include other post-marketing trials and clarified how "all other R&D direct costs" should be reported	Modify	Policy change in response to comments
ICR Form (Sections C and E, Questions 3, 5, and 10)	• Increased word limit because multiple questions were combined	Modify	Technical update
ICR Form (Section C, Question 5)	• Added definition and instructions	Modify	Change due to internal or administrative review
ICR Form (Section C, Questions 6, 6a, and 6b)	• Split question 6 into two components: 6a and 6b • Revised to add information previously in Section G to questions 6, 6a and 6b regarding global and U.S. net revenue metrics • Revised reporting of U.S. net revenue from quarterly to lifetime	Modify / Add	Policy change in response to comments

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
ICR Form (Section D)	• Revised manufacturer submission of production and distribution costs from NDC-9 to NDC-11 (CMS will aggregate multiple NDC-11s to NDC-9s)	Modify	Policy change in response to comments
ICR Form (Section D)	• Added description of "labeling"	Add	Changes due to internal or administrative review
ICR Form (Section E, Instructions)	• Revised to clarify how indirect costs should be considered • Revised to describe how responses to questions 9-11 should be calculated	Modify / Add	Changes due to internal or administrative review
ICR Form (Section E, Questions 9, 10)	• Revised language to include all funding in question 9 and to specify sources of the funding in question 10	Modify	Policy change in response to comments
ICR Form (Section F, Instructions)	• Revised description of relevant time period for reporting patent information	Modify	Policy change in response to comments
ICR Form (Section F, Question 12)	• Revised example language to illustrate the types of patents and patent applications about which CMS seeks information and modified response format for pending patent applications	Modify/Add	Policy change in response to comments

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ICR Form (Section F, Question 13)	• Revised language to clarify that manufacturers should describe patents for the selected drug that are listed in the FDA Orange or Purple Book	Modify	Technical change in response to comments
ICR Form (Section F, Question 12)	• Added example for submission of information on the purpose of a patent	Modify/Add	Technical change in response to comments
ICR Form (Section F, Question 14)	• Revised language to clarify that exclusivities are statutory and that FDA has not determined the first licensure for each 351(a)-biological product in the Purple Book	Modify	Technical change in response to comments
ICR Form (Section F, Question 15)	• Added language for manufacturers to submit any efficacy supplements that have been approved or are pending FDA approval	Modify/Add	Policy change in response to comments
ICR Form (Section F, Question 15)	• Removed column for manufacturers to enter submission number and modified response format for application status and classification code	Modify	Technical change in response to comments; Change due to internal or administrative review
ICR Form (Sections H-J	• Moved Certification of Submission of Sections A through G (formerly Section I) to follow section G; moved	Modify	Technical changes due to internal or administrative review

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
	Evidence on Alternative Treatments (formerly Section H) to section I		
ICR Form (Section H)	• Revised language to clarify which individuals of the Primary Manufacturer are eligible to certify the data submission	Modify	Changes due to internal or administrative review
ICR Form (Section I, Question 26)	• Revised language to capture additional types of respondents, including researchers and caregivers	Modify	Technical change in response to comments
ICR Form (Section I, Instructions for Questions 27-31)	• Revised language to clarify evidence and documentation requirements if evidence includes or is related to qualify-adjusted-life-years (QALYs) • Added language to clarify evidence and documentation requirements if evidence is related to cost-effective measures • Clarified instructions regarding use of citations • Added instructions pertaining to caregivers who may respond to questions in Section H	Modify / Add	Policy change in response to comments

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
	• Added instructions regarding the permissible submission of visual representations		
ICR Form (Section I, Instructions for Questions 27-31)	• Removed duplicate bullet regarding instructions for submission of materials • Added clarification of question instructions for unpublished material, citations and visual representations of information	Modify	Technical change due to internal review
ICR Form (Section I, Question 27)	• Added clarification of question instructions for off-label uses • Removed submission of FDA labels, as CMS is able to view this information	Add / Modify	Policy change in response to comments Technical change due to internal review
ICR Form (Section I, Questions 28-30)	• Added ability to submit visual representation of information (e.g., charts/tables/graphs)	Add / Modify	Policy change in response to comments
ICR Form (Section I, Questions 27-30)	• Added language to checkbox clarifying that the response also includes measures used in the evidence submitted	Add	Changes due to internal or administrative review
ICR Form (Section I, Question 28)	• Clarified language regarding outcome information requested	Modify / Add	Policy change in response to comments

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
	• Added language requesting key outcomes and explanation of selection • Added language regarding risks, harms, side effects or unique scenarios or considerations of the drug or therapeutic alternative		
ICR Form (Section I, Question 29)	• Revised to clarify individuals who are terminally ill and request explanation of specific populations noted • Added question regarding health equity considerations	Modify / Add	Policy change in response to comments
ICR Form (Section I, Question 30)	• Added a question regarding unmet medical need	Add	Policy change in response to comments
ICR Form (Section I, Question 31)	• Added a new question and corresponding instructions to capture patient and caregiver experiences related to the selected drug and/or therapeutic alternatives	Add	Policy change in response to comments
ICR Form (Section I, Question 32)	• Added a new question (required for manufacturers; optional for the public—except not permitted for patients/caregivers) for submission of an executive summary of information provided in response to questions 27-30	Add	Policy change in response to comments

Location of Edits[i]	Summary of Changes (Following 60-day Comment Period)	Type of Change	Explanation of Changes
ICR Form (Section J)	• Revised certification language for submissions of data in response to Section I	Modify	Policy change in response to comments

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