**Drug Price Negotiation for Initial Price Applicability Year 20XX**
**Under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR)**
**Crosswalk of Changes Between Initial Price Applicability Year 2028 and Proposed 60-day Version Documents***

| Location of Edits | Summary of Changes (Included in Final) | Type of Change | Explanation of Changes | Burden Change (Yes/No) |
|---|---|---|---|---|
| Supporting Statement | | | | |
| Throughout | • Revisions to include references to applicable policies proposed to be codified in the Negotiation Program notice of proposed rulemaking (CMS-4215-P) (hereinafter, the "Negotiation Program NPRM")<br>• Revisions to amend initial price applicability year references from "initial price applicability year 2028" to "initial price applicability year 20XX" and/or references to NPRM terms (e.g. calendar year prior to the selected drug publication date for the applicable initial price applicability year) because CMS intends to incorporate non-substantive date revisions to within the ICR Forms upon review and approval of the package from the Office of Management and Budget annually for each initial price applicability year<br>• Addition of information to incorporate the Small Biotech Floor ICR Form, pursuant to section 1194 of the Social Security Act (the "Act")) | Modify | Revisions consistent with the statutory requirements at section 1194 of the Act; Technical updates | No |
| Burden Estimate | • Addition of burden for the Temporary Floor for Small Biotech Drugs ICR Form<br>• Revision of the number of respondents estimated for the Negotiation Data Elements and the Counteroffer Process ICR Forms based on the number of selected drugs that may be potentially selected for renegotiation for one year of submission based on the example of initial price applicability year 2029 as the base year<br>• Revisions to update the burden estimates for submitters to incorporate the average labor costs using the May 2025 data from the Bureau of Labor Statistics<br>• Revisions to update the government burden estimate to incorporate 2026 federal pay scales<br>• Revisions to update table numbers and formatting of government cost estimate tables | Modify | Revisions consistent with the statutory requirements at section 1194 of the Act; Technical updates | Yes |
| Information Collection Request (ICR) Forms | | | | |

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|---|---|---|---|---|
| ICR Form – Negotiation Data Elements | | | | |
| Throughout | • Revisions to include references to applicable policies proposed to be codified in the Negotiation NPRM<br>• Revisions to update calendar year references to include placeholder dates applicable to the collection of information for each initial price applicability year (e.g. 20XX) and/or references to NPRM terms (e.g. calendar year prior to the selected drug publication date for the applicable initial price applicability year)<br>• Renumbering of questions due to revisions in Sections F and G | Modify | Revisions consistent with the statutory requirements at section 1194 of the Act; Technical updates | |
| Sections C and E | • Revision to specify that the instruction related to research and development (R&D) costs incurred on or before the last date of the Primary Manufacturer's original full submission of section 1194(e)(1) data applies to any Primary Manufacturers of drugs originally selected for negotiation for initial price applicability years 2026 or 2027 only | Modify | Technical updates | No |
| Sections D, F and G | • Addition of instructions to specify the time period of data requested for drugs originally selected for negotiation for the drugs selected for the most recent prior initial price applicability year (which is initial price applicability year 2028) | Modify | Revisions consistent with the statutory requirements at sections 1194(e)(1) and (f)(4) of the Act | Yes |
| Section F | • Revisions to the response format for Questions 9A, 9B and 10 to accommodate text responses in the patent type<br>• Addition of Question 12 regarding the predicted loss of exclusivity for the selected drug | Modify | Revisions consistent with the statutory requirements at sections 1192(e)(1) and (f)(4) of the Act | Yes (regarding addition of question only) |
| Section G | • Revisions to the numbering of questions throughout the section<br>• Revisions to the instructions for reporting Average Sales Price (ASP) in response to Question 14 when a drug is not payable under Part B<br>• Addition of Questions 27 regarding the payer mix of prescriptions for the selected drug by indication<br>• Addition of Question 28 to report the agreed-to maximum fair price of the selected drug from the original negotiation | Modify | Revisions consistent with the statutory requirements at sections 1194(e)(1) and (f)(4) of the Act | Yes (regarding addition of questions only) |
| Section I | • Revisions to the numbering of questions throughout the | Modify | Technical updates and | Yes (regarding |

| Location of Edits | Summary of Changes (Included in Final) | Type of Change | Explanation of Changes | Burden Change (Yes/No) |
|---|---|---|---|---|
| | section<br>• Addition of Question 35 to report medical needs related to condition(s)<br>• Addition of Question 55 to request therapeutic advance and unmet medical need from researcher respondents<br>• Addition of costs associated with therapeutic alternatives for Question 41<br>• Clarifying revisions to question prompts for Questions 31, 32, 33, 34, 40, 41, 45, 46, 48, 52, | | revisions consistent with the statutory requirements at section 1194(e)(2)(A) | addition of questions only) |
| ICR Form – Temporary Floor for Small Biotech Drugs | | | | |
| Throughout | • Addition of the form pursuant to section 1194 of the Act | Modify | Revisions consistent with the statutory requirements at section 1194 of the Act | Yes |
| ICR Form – Counteroffer Process | | | | |
| Throughout | • Revisions to include references to applicable policies proposed to be codified in the Negotiation NPRM<br>• Revisions to update calendar year references to include placeholder dates applicable to the collection of information for each initial price applicability year (e.g. 20XX) and/or references to NPRM terms (e.g. calendar year prior to the selected drug publication date for the applicable initial price applicability year) | Modify | Technical updates | No |
| Instructions | • Revisions to the instructions to clarify submission requirements for citations and visual representations | Modify | Technical updates | No |
| Question 2 | • Revisions to Question 2 to remove the response field for submission of citations and visual representations<br>• Addition of Question 3 and 4 for submission of citations and visual representations, respectively | Modify | Technical updates | No |
| Certification | • Revisions to certification language to include mention of civil monetary penalties pursuant to section 1197(c) of the Act. | Add | Revisions consistent with the statutory requirements at section 1197(c) of the Act | No |

*Question numbering matches 60-day document.