

Rebate Reduction Requests 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	Impact to Burden
Supporting Statement	Moved the description of the purpose of the ICR to the beginning of the document so that it precedes the “Background” section	Modify	Technical change	None
Supporting Statement, “Background”	Added language explicitly stating that this ICR does not address rebate reductions for Part B and Part D rebatable drugs currently in shortage	Add	Technical change	None
Supporting Statement (Federal Register)	Revised language consistent with publishing a revised package for a 30-day public comment period	Modify	Technical change	None
Supporting Statement “Burden Estimates (Hours & Wages)”	Updated Tables 1 through 5 to use the data from the Bureau of Labor Statistics’ May 2023 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing rather than the 2022 data	Modify	Calculation changes due to source update	Increased median hourly wages
Supporting Statement “Cost to Federal Government”	Updated Table 6 to use the data from the 2024 General Schedule Locality Pay Tables published by the Office of Personnel Management for the Washington-Baltimore-Arlington region rather than the 2023 data	Modify	Calculation changes due to source update	Increased median hourly wages
ICR Form (Appendix C and D), General Instructions	Revised example of when a generic Part D rebatable drug is likely to be in shortage to clarify that supply of the drug is “unlikely to meet demand”	Modify	Technical change	None
ICR Form (Appendix A), Submission method; ICR	Added language in the submission method to clarify a natural disaster or other unique or unexpected event “that the manufacturer	Add	Technical change	None

Form (Appendix B), Submission method	believes caused a severe supply chain disruption”			
ICR Form (Appendix A), Submission requirements and Q5; ICR Form (Appendix B), Q6	Added “contract manufacturer” to entities impacted by a severe supply chain disruption and added a definition for “contract manufacturer.”	Add	Change in response to comments	None
ICR Form (Appendix C), Submission requirements; ICR Form (Appendix D), Submission requirements	Added “contract manufacturer” and “or similar supply chain issues that could foreseeably limit the supply or manufacturing of the drug” to the examples of evidence for a likely shortage and added a definition for “contract manufacturer.”	Add	Change in response to comments	None
ICR Form (Appendix A, B, C, and D), Certification	Added “the unique identifier(s) assigned by CMS within the Health Plan Management System (HPMS)” to clarify P-numbers	Add	Technical change	None
ICR Form (Appendix A), Q7; ICR Form (Appendix B) Q8; ICR Form (Appendix C), Q7; ICR Form (Appendix D), Q8.	Revised question to clarify that the manufacturer should identify information which it believes to be considered proprietary, but CMS will itself determine whether the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)).	Modify	Technical change	None
ICR Forms (Appendix A, B, C, and D) (throughout)	Revised “60 days” to “60 calendar days” where “calendar” was missing for clarification	Add	Technical change	None

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