

Crosswalk: 340B Repository Data Elements Reporting Instructions

This Crosswalk identifies the changes that were made **subsequent to** the publication of our July 16, 2025 (90 FR 32352) proposed rule's (CMS-1832-P, OMB 0938-AV50) collection of information request.

The changes are in our November 5, 2025 (90 FR 49266) final rule's (CMS-1832-F, OMB 0938-AV50) collection of information request.

Location of Edits	Summary of Changes	Type of Change	Explanation of Changes	Burden Change (Yes/No)
Submission Method	Clarification that there is not a required attestation for the submitter of the Part D 340B claims data file, only a certification.	Modify	Technical Updates	No
Submission Method	Updated to reflect that CMS will not "append a submission timestamp" but rather "maintain data" to assist in records management, downstream processing, and de-duplication of submissions, as needed.	Modify	Technical Updates	No
Submission Method	CMS updated that in response to commenters feedback, CMS intends to develop a submission method that is standardized, based on future file layout instructions provided by CMS, and created in a way that minimizes burden for covered entities.	Modify	Technical Updates	No
Definitions	Added clarifying instructions for how covered entities that are not registered in the 340B OPAIS should populate the "340B Name" and "340B ID" fields when submitting data elements.	Modify	Technical Updates	No
Definitions	Added clarification to the identifiers "340B Name" and "340B ID" to "Covered Entity Name" and "Covered Entity 340B ID" to align with description in the Example Form.	Modify	Technical Updates	No
Form Title	Removed the term "Appendix A" from the form title.	Modify	Technical Updates	No