

60-Day Comment Response Document

Overview of Comments

CMS received comments from four Part D sponsors regarding the following sections from the Data Validation Procedure Manual: Data Validation Requirement and DV Review Findings

Detailed Summary of Comments

Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
DV Procedure Manual, 1.1 Data Validation Requirement	Two commenters disagree with the proposal to move the end date of the data validation review period from June 30 to June 15 because more time is needed to complete all tasks and review before submission.	Request to maintain current data validation time period April 1 - June 30	CMS's changes to streamline the data validation process will support a shortened review period. Additionally, the earlier deadline in June will allow sponsors time to request an appeal, should there be disputes or unresolved issues with their DV results. For these reasons, CMS will continue to propose the June 15th deadline.	No	No
DV Procedure Manual, 5.3.1 DV Review Findings	Two commenters request CMS not eliminate the ability currently for a sponsor and DVC to review draft DV findings prior to submission. Such reviews allow issues to be resolved in the early stages of DV, e.g. additional documentation if DVC findings are inconsistent with SO-submitted documentation.	Request to revert to the current DV manual language permitting this review process.	CMS will allow SOs to review preliminary findings, but review of findings should be limited to technical corrections for factual accuracy. The DV audit must be conducted independently by the DVC. Therefore, DVCs should not make and SOs should not suggest changes to findings based on new data not submitted timely to DVCs or request changes that are not supported by evidence. If organizations are not satisfied with the findings, SOs may follow the appeal process outlined in the DV Manual.	Yes	No