Revisions to 2nd Draft of CY2010 Part D Reporting Requirements

Thirteen organizations submitted 116 comments to the 1st draft of the Part D CY2010 Reporting Requirements. The table below summarizes the revisions made for the 2nd draft of the CY2010 Part D reporting requirements.

The revised package also includes burden estimates for Plans' collection of documentation necessary for Plans' self-auditing of reported data. The requirements for plan auditing will be introduced as a phased-in approach over the next three years; in total, seventeen reporting sections will be impacted, with an additional reporting burden of 30 minutes per section, or a total of 8.5 hours annually. Since plan auditing requirements will be phased in, this burden will not be fully realized until all requirements have been issued by CMS. Further, the reporting burden applies to new Part D plans; plans that continue to offer the Part D benefit will have a diminished reporting burden as audit and reporting requirements remain fixed. The following reporting sections are excluded from Plan auditing requirements because the data are already audited via other means: Generic drug utilization; Licensure and Solvency; Pharmaceutical Rebates; and Fraud, Waste, and Abuse Compliance Programs.

#	Category	Section	Change/Reason	Effect to reporting burden
1	Response to Public Comments	Enrollment	Clarification provided to data elements, including inclusion and exclusion criteria for data to be reported.	None
2	Response to Public Comments	Retail, Home Infusion, and Long-term Care Pharmacy Access	Subsection numbering errors were corrected.	None
3	Response to Public Comments	Retail, Home Infusion, and Long-term Care Pharmacy Access	A statement was added to subsection D to clarify that plans receiving waivers for retail pharmacy convenient access standards would no longer be exempt from submitting data elements A1-A4. The 1st draft had only struck the statement that these plans were exempt from reporting. It is more clear to state this change in reporting.	Increase
4	Response to Public Comments	Access to Extended Day Supplies at Retail Pharmacies	Data element B, the number of contracted retail pharmacies in a Contract's service area, was deleted, and a statement was inserted that data reported in the Retail, Home Infusion, and Long-term Care Pharmacy Access section would be used instead. This will avoid duplicative reporting.	Decrease
5	Response to Public Comments	Vaccines	The 2nd reporting period was revised to a 12 month year-to-date (YTD) period from a 6 month period. This change addresses concerns that some vaccine claims would fall between 6 month	None

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			reporting periods due to differences between vaccine administration and adjudication dates. Plans report vaccines based on administration dates within a reporting time period; lags in adjudication time could result in plans receiving claims after submitting data for the 1st 6 month reporting period. It would be inaccurate to include those claims in the 2nd 6 month reporting period. The 12 month YTD period will allow Plans to adjust these data to accurately reflect vaccine administrations.	
6	Response to Public Comments	Medication Therapy Management Programs	Subsection I, data element K, the average amount of time spent to complete an annual comprehensive medication review per MTMP enrollee, was deleted to reduce unnecessary reporting burden.	Decrease
7	Response to Public Comments	Medication Therapy Management Programs	Subsection II, data element N, the term provider was replaced with prescriber. This terminology is consistent with other CMS issued guidance.	None
8	Response to Public Comments	Medication Therapy Management Programs	Subsection II, data elements O-T were combined into a revised data element O, the number of changes to drug therapy made as a result of MTM interventions, in order to reduce errors or inconsistency in data.	Decrease
9	Response to Public Comments	Medication Therapy Management Programs	In subsection II, the term “direct result” was revised to “result”. Comments indicated the term direct was difficult to interpret.	None
10	Response to Public Comments	Prompt Payment by Part D Sponsors	Clarification was made to the term “days” to refer to calendar days, and non-electronic claims included paper claims.	None
11	Response to Public Comments	Pharmacy Support of Electronic Prescribing	Data elements A and C, the numbers of retail pharmacies and non-retail pharmacies in a contract’s service area, were deleted. Instead, a statement was inserted that the data reported in the Retail, Home Infusion, and Long-term Care Pharmacy Access section would be used instead to evaluate these data. This will avoid duplicative reporting.	Decrease
12	Response to Public Comments	Generic Drug Utilization	Clarification was made that claims for non-drug products (e.g. alcohol pads) should be excluded.	Decrease
13	Response to Public Comments	Grievances	For improved clarity, the data elements were reformatted.	None
14	Response to Public Comments	Grievances	To reduce burden, the core category of fraud, waste, and abuse grievances was removed, as these are included in the Fraud,	None

#	Category	Section	Change/Reason	Effect to reporting burden
			Waste, and Abuse Compliance Programs reporting section. In this reporting section, those types of grievances will be counted in the "Other" category.	
15	Response to Public Comments	Grievances	Collecting the number of grievances that did not have timely notification were removed, as Plans already report the total number of grievances and the number that did receive timely notification. The number of grievances that did not have timely notification can be calculated from the plan reported data.	Decrease
16	Response to Public Comments	Coverage determinations and Exceptions	Data elements were revised to clarify if certain data elements were subsets of total(s).	None
17	Response to Public Comments	Coverage determinations and Exceptions	Data elements E and F, total number of non-prior authorization coverage determinations requested and approved in the time period, were deleted, as comments indicated that these could be interpreted as being included in other data elements (G-L).	Decrease
18	Response to Public Comments	Appeals	Data element B, the number of requests for redeterminations dismissed by the Plan, was deleted as Plans rarely dismiss redetermination requests. Data element A was revised to state the total number of redeterminations processed in the time period.	Decrease
19	Response to Public Comments	Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	A sentence was struck in the introduction of this section that referred to the previous quarterly reporting; data for this section is now reported annually.	None
20	Response to Public Comments	Long-term Care Utilization	Definitions were provided to clarify terms. For consistency, the terms "licensed to serve" were deleted, and the term "contracted" was replaced with network. The method of data submission was changed to upload into HPMS instead of data entry.	None
21	Response to Public Comments	Long-term Care Utilization	The term "non-LTC" was replaced with retail, as comments indicated this term was not clear.	None
22	Correction	Licensure and Solvency	Revisions were made to update this section to include the non-material changes approved by OMB to the CY2009 reporting requirements. The basis for these changes was that data would no longer be mailed to CMS, or entered into the Plan reporting module	None

#	Category	Section	Change/Reason	Effect to reporting burden
			in HPMS. Instead, these data are uploaded or entered into the Fiscal Soundness module in HPMS.	
23	Response to Public Comments	Fraud, Waste and Abuse Compliance Programs	Reporting for this section was revised to be voluntary. Clarification was added that CMS is collecting aggregate data. Clarification, including examples, were also provided for some data elements.	Decrease
24	Response to Public Comments	Employer/Union-Sponsored Group Health Plan Sponsors	For consistency with the Part C reporting section, two data elements, Contract ID and Plan ID, were deleted, and clarification was added to some data elements. The HPMS will already electronically map the data submissions to the submitting contract and plan.	None
25	Correction	Agent Training and Testing	Section added, per previous notice in Part C Reporting Requirements.	Increase
26	Correction	Plan Oversight of Agents	Section added, per previous notice in Part C Reporting Requirements.	Increase