

## Revisions from 60-day Comment Period to CY 2008 Part D Reporting Requirements

### Summary:

- Compared to the first draft of the CY2008 reporting requirements posted for public comment, the current CY2008 reporting requirements document is associated with a decreased reporting burden as a result of the changes made after the 60 day comment period. Specifically, the frequency of reporting was decreased for one reporting section (Section I - Retail, Home Infusion and Long-Term Care Pharmacy Access), as well as two data elements were deleted (Section VII - Home Infusion Utilization)

Category	Section	Change/Reason	Effect to reporting burden
Lessons learned	All	Where applicable, the term Part D Contract was replaced with Part D Sponsor. The term Part D Contract had sometimes caused confusion.	No change in burden
Response to Public Comments	Section I - Retail, Home Infusion and Long-Term Care Pharmacy Access	Reduction in the reporting frequency for subsections A and B. Data from one quarter only will be collected on an annual basis. Previously, data would be collected and submitted biannually.	Decrease in burden
Lessons learned	Section I - Retail, Home Infusion and Long-Term Care Pharmacy Access	Clarification was added to exclude PACE organizations from reporting data for subsections A and B. This is consistent with other reporting sections which exclude PACE organizations from reporting.	No change in burden
Lessons learned	Section I - Retail, Home Infusion and Long-Term Care Pharmacy Access	Addition of two subsections C and D only for those Part D Sponsors which received waivers for any willing pharmacy requirement and/or the retail convenient access requirement after the initial pharmacy access submission. Those Sponsors will submit these data at the Plan (PBP) level, on an annual basis. These subsections are necessary given the information collected by subsection A of this reporting section.	Increase in burden
Lessons learned	Section I - Retail, Home Infusion and Long-Term Care Pharmacy Access	Subsection B revised to state tab delimited text files will be uploaded. Excel files had previously been listed as the type of files to be uploaded, however tab delimited text files are required by the application to which they will be uploaded.	No change in burden
Response	Section III -	Clarifications were made to data elements A-D. A correction was	No change in burden

<b>Category</b>	<b>Section</b>	<b>Change/Reason</b>	<b>Effect to reporting burden</b>
to Public Comments	Vaccines	made to data element F.	
Response to Public Comments	Section V - Medication Management Therapy Programs	The reporting timelines for both subsections were revised to list YTD instead of Period 2.	No change in burden
Lessons learned	Section V - Medication Management Therapy Programs	Subsection B was revised to state that tab delimited text files will be uploaded. Additionally, this statement was added: "Part D Sponsors will upload files using Gentran or Connect Direct. More information regarding the upload will be forthcoming." A record layout was provided. Excel files had previously been listed as the type of files to be uploaded, however tab delimited text files are required for efficient submission by Sponsors.	No change in burden
Response to Public Comments	Section V - Medication Management Therapy Programs	Addition of a field in the text file to indicate if a MTM participant was a LTC resident. Other fields' labels were clarified.	Increase in burden
Response to Public Comments	Section VII - Home Infusion Utilization	The term "home infusion drug" was defined.	No change in burden
Response to Public Comments	Section VII - Home Infusion Utilization	Data elements A and B were deleted. Data element D was clarified.	Decrease in burden
Response to Public Comments	Section VIII- Grievances	Clarification was made that plans should not dismiss or exclude any grievances filed by beneficiaries or their appointed representatives from this reporting section.	No change in burden
Response to Public Comments	Section X - Transition	Clarification was made that only one quarter of data would be collected and reported annually.	No change in burden
Lessons learned	Section XI - Exceptions	Clarification was made to include prior authorization requests/approvals that relate to Part B vs. Part D coverage. Previously, Sponsors were instructed to exclude these types of requests/approvals from this reporting, and this potentially caused	No change in burden

Category	Section	Change/Reason	Effect to reporting burden
		inaccuracies.	
Lessons learned	Section XIV - Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	Correction that tab delimited text files will be uploaded. Excel files had previously been listed as the types of files to be uploaded, however tab delimited text files are required by the application to which they will be uploaded.	No change in burden
Lessons learned	Section XV - Long-Term Care (LTC) Rebates	Correction that tab delimited text files will be uploaded, and should include character fields. Excel files had previously been listed as the types of files to be uploaded, however tab delimited text files are required by the application to which they will be uploaded. Instructions for reporting special cases were added. As these instructions became effective for CY2007, they must be included for CY2008.	No change in burden
Lessons learned	Section XVI - Licensure & Solvency	The terms "Part D Employer/Union Only Group Waiver" were replaced with "Employer/Union Direct Contract", and "Direct EGWPs" replaced with "Direct Contract PDP". The previous terminology had sometimes caused confusion.	No change in burden
Lessons learned	Section XVI - Licensure & Solvency	Move of Subsection IV. Performance of Part D Activities data to Pharmacy & Therapeutics (P&T) Committees Section. In CY2007, this subsection was created as an extension of the business and financially related data elements reported. It is, however, more closely related to the data reported in the P&T Committees section.	No change in burden