Issue #	Page #	Section	Action to be performed	Changes to the Application	Reason for the Change
1.	2	Table of Contents	Addition of four new sections, name change for one section, and the deletion of one section	 The addition of Section I. (Retail, Home Infusion, and Long Term Care Pharmacy Access), Section II. (Access to Extended Day Supplies at Retail Pharmacies), and Section III. (Vaccines) and VII. (Home Infusion Utilization) Section VI's name changed from Generic Dispensing Rate to Generic Utilization The Section called Call Center Measures: Beneficiary Service line and Pharmacy Support line was deleted for CY 2008 	These changes reflect the changes in the CY 2008 Reporting Requirement document.
2.	3	Introduction	Addition of four new sections, name change for one section, and the deletion of one section	 The addition of Section I. (Retail, Home Infusion, and Long Term Care Pharmacy Access), Section II. (Access to Extended Day Supplies at Retail Pharmacies), and Section III. (Vaccines) and VII. (Home Infusion Utilization) Section VI's name changed from Generic Dispensing Rate to Generic Utilization The Section called Call Center Measures: Beneficiary Service line and Pharmacy Support line was deleted for CY 2008 	The introduction describes the Sections that are in the reporting requirement document. The section additions, section name change and section deletion need to be changed in the introduction to properly portray the sections described in the document.
3.	4	Introduction	Addition of four new sections and name change for one section for PACE Organizations	The addition of Vaccines and the name change for Generic Drug Utilization was included in the introduction that discusses PACE Organizations responsibilities.	The introduction specifies the sections that are applicable to PACE Organizations.

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					These additions/name changes must be updated appropriately.
4.	4	Introduction	Addition of another element in which two decimal places are acceptable	In the data format section, there is clarification that all data should be reported at the nearest whole number with the exception of the number of covered Part D 30-day equivalent prescriptions in the Medication Therapy Management Program (MTMP) section and the Rebate \$ per unit received in the Long-Term Care (LTC) Rebate section. The MTMP section will be entered to two decimal places and the LTC element will be entered to four decimal places	In order to adequately evaluate the Rebate \$ per unit for the LTC rebate, this data element need to have the availability to be entered to the fourth decimal place.
5.	5	Section I. Retail, Home Infusion, and Long-Term Care Pharmacy Access	New section added	Retail, Home Infusion, and Long-Term Care Pharmacy Access section added for data element collection.	The addition of this data element will allow CMS to evaluate Part D Contracts' continued compliance with pharmacy access requirements.
6.	7	Section II. – Access to Extended Day Supplies at Retail Pharmacies	New section added	Access to Extended Day Supplies at Retail Pharmacies section added for data element collection.	This new section will monitor to ensure that enrollees have reasonable access to the same extended day supply benefits at retail that are available at mail order pharmacies.

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7.	8	Section III. –	New section added	Vaccines section added for data	The Vaccines reporting
		Vaccines		element collection.	section will demonstrate
					CMS' guidance on
					Vaccines.
8. 9	99	Section IV	Level of Reporting	The level of reporting will be Contract	Changing the level of
		Reversals		or Plan compared to Contract in CY	reporting will provide a
				2007	more detailed review of
0	0	Castian IV	Clarification to Element	The definition of out of such has	reversals.
9.	9	Section IV Reversals	Clarification to Element	The definition of out-of-cycle has been added to data element A.	The out-of-cycle definition
		Reversals	A	been added to data element A.	will provide Sponsors more detail information.
10.	10	Section V. –	New requirement	The addition of data element H. Data	The addition of data
10.	10	Medication		element H is the number of	element H will capture the
		Therapy		beneficiaries who discontinued	number of beneficiaries
		Management		participation from the MTMP for a	that have discontinued for
		Programs		reason not specified in data elements	other reasons not already
				E-G during the specified time period	requested. This data
				above. This should be a subset of the	element will facilitate in
				total number of beneficiaries who	monitoring the reasons for
				discontinued participation from the	a beneficiaries
				MTMP in the specified time period.	discontinued participation.
11.	10	Section V. –	New requirement	The addition of data element J. Data	The request for the number
		Medication		element J is the number of	of beneficiaries that are
		Therapy		beneficiaries whose participation	pending during a certain
		Management		status in the MTMP is pending during	period of time will provide
		Programs		the specified time period above. This	CMS will a more complete
				should be a subset of the number of	picture of the number of
				beneficiaries who met the criteria for	beneficiaries eligible for the MTMP.
				the MTMP in the specified time period.	
12.	11	Section V	Change to formula	Data element L's formula has been	The formula has been
		Medication		revised to have "Days Supply" divided	revised to accurately depict
		Therapy		by 30.	the data element.
		Management			
		Programs			

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13.	11	Section V Medication Therapy Management Programs	New HPMS data file upload	A data upload for beneficiaries identified as being eligible for the Medication Therapy Management Program is new in CY2008.	The data upload information will facilitate the monitoring of beneficiaries in MTM programs.
14.	13	Section VI Generic Drug Utilization	Change in Section name	Generic Dispensing Rate changed to Generic Drug Utilization	The name of this section was changed to more accurately reflect the data in this section.
15.	13	Section VI Generic Drug Utilization	Revision of requirement statements	Elements A and B requirement statements have been revised to ask for "total number" of paid claims	The addition of text was added to provide clarification to these data elements.
16.	14	Section VII Home Infusion Utilization	New section added	Home Infusion Utilization section added for data element collection.	These data will be monitored by CMS for purposes of assessing enrollee utilization of and access to home infusion therapy.
17.	15	Section VIII. - Grievances	Addition of example in description	The example of "enrollment/disenrollment issues or recognition of low income subsidy (LIS) eligibility problems" was added to the Grievances description.	These additional examples provide further clarification of a grievance.
18.	15	Section VIII. - Grievances	Clarification to data element A	The addition "Plan Agent" added to element A as an example of entity against whom a fraud grievance can be made.	These additional examples provide further clarification of a grievance.
19.	15	Section VIII. - Grievances	Clarification to data element E	"Overly aggressive marketing" added to element E as an example of a marketing grievance.	These additional examples provide further clarification of a grievance.
20.	16	Section VIII. - Grievances	New requirement	Element M is a new requirement addressing LIS related grievances.	The addition of element M provides monitoring information specifically related to LIS related grievances.

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21.	17	Section IX Pharmacy & Therapeutics (P&T) Committees	Element statement and instructions revised	Element A has been revised to indicate if changes to P&T committee had been made during specified reporting periods. The text referring to a drop down box has been removed also for elements A and B.	The change provides appropriate information for the range of data and the method to indicate such data.
22.	18	Section X Transition	Introduction statement revised	Revised introduction statement: As described in §423.120(a)(3) and <u>section 30.4</u> of Chapter 6 of the Prescription Drug Benefit Manual, Part D Plans must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on the plan's formulary. For purposes of CMS oversight, Plans (PBPs) will be responsible for reporting various data elements related to minimum plan transition process timeframes on an annual basis. In addition, Plans (PBPs) will be responsible for reporting various data elements related to prescriptions for transition supplies dispensed during newly enrolled beneficiaries' transition periods on an annual basis.	The revised introduction accurately reflects the changes made to the data elements.
23.	18	Section X. Transition	Data elements revised completely	Data element A: The minimum number of days supply the Plan's transition policy provides for its one- time, temporary fill for enrollees in the retail setting. (NOTE: This must be at least 30 days, unless the enrollee presents with a prescription written for less than 30 days). Data element B: The minimum number of days, beginning on the	These data elements have been revised to monitor data related to minimum plan transition process timeframes and data related to transition supplies dispensed during a newly enrolled beneficiaries' transition period.

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				enrollee's effective date of coverage,	
				in a plan's transition process for	
				enrollees in the retail setting. (NOTE: This must be at least 90 days.)	
				This must be at least 50 days.)	
				Data element C: The minimum	
				number of days supply the Plan's	
				transition policy provides for its	
				temporary fill (with multiple refills as	
				necessary) for enrollees in the LTC	
				setting. (NOTE: This must be at least	
				31 days, unless the enrollee presents	
				with a prescription written for less	
				than 31 days).	
				Data element D: The minimum	
				number of days, beginning on the	
				enrollee's effective date of coverage,	
				in a plan's transition process for	
				enrollees in the LTC setting. (NOTE:	
				This must be at least 90 days.)	
				Data element E: After the minimum	
				transition period has expired, the	
				minimum number of days supply the	
				Plan provides to LTC enrollees for an	
				emergency supply of non-formulary Part D drugs while an exception is	
				being processed (NOTE: This must	
				be at least 31 days, unless the enrollee	
				presents with a prescription written for	
				less than 31 days).	
				Data element F: The maximum	
				number of business days after a	
				temporary transition fill within which	
				the Plan will send a written transition	
				notice via U.S. first class mail.	

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				(NOTE: This must be 3 business days or less.)	
				Deletion of data elements from CY2007.	
24.	19	Section XI Exceptions	Data elements revised	Data elements D and E have added "quantity limits" text as an example of information that should not be included.	The addition of this example provides further clarification of the data element.
25.	20	Section XII Appeals	Clarification added to data element A	A clarification "Do not include those appeals that were submitted as expedited redeterminations and were not granted expedited status."	This descriptive sentence will provide additional clarification.
26.			Call Center Measures section from 2007 deleted	Call Center Measures: Beneficiary Service line and Pharmacy Support line deleted	The Call Center Measures section has been deleted from CY2008. To ensure data is consistent among all Sponsors, CMS will continue to monitor Call Center Measures via a CMS contractor.
27.	22	Section XIII. – Overpayment	Clarification to data elements	Deleted words provide and this should be a currency field.	Revised for consistency.
28.	25	Section XV Long-term Care (LTC) Rebates	Addition of text for each upload element to indicate if the field should be a text or numeric.	Each data element provides the description of the type of field.	The helps to provide clarification.
29.	25	Section XV Long-term Care (LTC) Rebates	New requirement	Addition of data element #6 - NDC: Provide the 11-digit NDC associated with this rebate. This should be a numeric field.	This additional element is necessary for the oversight and monitoring of Long- term Care Rebates.
30.	25	Section XV Long-term	Revised definition of element #6 under A.	The description of element #6 is "Drug name: Provide the brand name.	The change in element #6 defines the definition of

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		Care (LTC) Rebates		This should be a text field."	Drug name in this section.
31.	27	Section XVI. - Licensure and Solvency, Business Transactions and Financial Requirements	Description revised	The description paragraph has added verbiage such as "Part D or Union- Only". Additionally the sentence "Direct EGWPs are employers or unions that directly contract with CMS to offer a Part D plan exclusively to the employer's/union's retirees." was added to the description.	These additions provide clarification to this section.
32.	27	Section XVI. - Licensure and Solvency, Business Transactions and Financial Requirements	Subsection I – data element D – revised wording	Data element D now reads: According to the quarterly time periods specified above, Part D PDP Sponsors not licensed in any state must submit documentation that demonstrates they possess the allowable sources of funding to cover projected losses for the greater of 7.5% of the aggregated projected target amount for a given year or resources to cover 100% of any projected losses in a given year. This documentation should include a worksheet indicating how they arrived at the aggregated projected target amount. Pro-forma financial statements including the balance sheet, income statement and statement of cash flows projecting through the next 12 months by quarter. Enrollment projections through the next 12 months by quarter. Guarantees, letters of credit and other documents essential to demonstrating that the funding for projected losses requirement has been met must also be	This data element was revised to provide additional descriptive language.

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				included.	
33.	28	Section XVI. - Licensure and Solvency, Business Transactions and Financial Requirements	Subsection I – data element E added an additional sentence	The sentence "Licensed entities may not report under GAAP for a period longer than 36 months." was added to element E.	This additional sentence to data element E provides additional explanatory language.
34.	28	Section XVI. - Licensure and Solvency, Business Transactions and Financial Requirements	Subsection I – revision of wording in data element G.	According to the quarterly time periods specified above, Part D PDP sponsors with any state licensure waivers must submit an update on the status of obtaining licensure for each waived state.	Language was revised to more accurately depict this data element.
35.	28	Section XVI. - Licensure and Solvency, Business Transactions and Financial Requirements	Subsection I – Addition of verbiage in data element H.	Data element H now references § 423.514.	The addition provides a reference for this data element.
36.	29	Section XVI. - Licensure and Solvency, Business Transactions and Financial Requirements	Subsection II – language added to the address.	"All" was added to the address direction.	This language was added to clarify that All Direct EGWP documentation should be mailed to the appropriate address.
37.	29	Section XVI. - Licensure and	Subsection III – subsection description revised.	The subsection description is now " <u>Financial and Solvency</u> <u>Requirements data elements to be</u>	The change clarifies that this section applies to Direct EGWPs.

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		Solvency,		<u>entered into HPMS – For Part D</u>	
		Business		PDP Contracts / Direct EGWPs:".	
		Transactions			
		and Financial			
		Requirements			
38.	29	Section XVI.	Subsection IV – element	Element A had the additional language	The additional language
		- Licensure	A language revised.	of "during the quarterly reporting	confirms the time period of
		and		period" added.	the data.
		Solvency,			
		Business			
		Transactions			
		and Financial			
		Requirements			
39.	29	Section XVI.	Subsection IV – element	The words "This will be a selection	The language was revised
		- Licensure	A and B language	from a drop-down box" has been	for consistency.
		and	revised.	removed.	
		Solvency,			
		Business			
		Transactions			
		and Financial			
		Requirements			
40.	30	Section	Timeframe for collection	The collection of data is now monthly	In terms of monitoring and
		XVII Drug	of data	for CY2008	oversight, a need was
		Benefit			identified to collect data on
4.1	20	Analyses			a more frequent basis.
41.	30	Section	Description revised:	The section overview now includes	The additional language
		XVII Drug		the following explanatory sentence: If	provides a description of
		Benefit		a PBP does not have a deductible,	what a Sponsor can expect in HPMS if the PBP does
		Analyses		HPMS will not display data fields A	
40	30	Section	Descriptions revised	or B. Existing descriptions had the word	not have a deductible.
42.	30		Descriptions revised	Provide removed.	This change facilitated in the flow of the document.
		XVII Drug Benefit		Plovide lenioved.	the now of the document.
43.	30	Analyses Section	Now requirement	These data elements were added to	These data elements were
43.		Section XVII Drug	New requirement	this Section:	added monitor the phase of
		Benefit			LIS beneficiaries.
		Dellefit			LIS Demenciariles.

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		Analyze		Data element A: Total number of non- LIS enrollees in the deductible phase	
				as of the last day of the month.	
				Data element B: Total number of LIS enrollees in the deductible phase as of the last day of the month.	
				Data element D: Total number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the month	
				Data element F: Total number of LIS enrollees in the coverage gap as of the last day of the month	
				Data element H: Total number of LIS enrollees in the catastrophic coverage level as of the last day of the month.	