Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
SilverScript Insurance Company/SSLLC	Access to Extended Day Supplies at Retail Pharmacies	Data Element B, the number of contracted retail pharmacies in a Contract's service area, is duplicative to data reported in Section II. Duplicate data elements result in duplicated time and effort by the Plans.	Do not require that the same data are reported more than once. CMS should utilize data already provided in other sections or reports.	Accept	Data element B will be deleted.	edit
AHIP	Access to Extended Day Supplies at Retail Pharmacies	PDPs and regional PPOs. This section requires that Part D plan sponsors that include in their networks mail-order pharmacies offering extended day supplies of covered Part D drugs submit data that will allow CMS to evaluate access to extended day supplies at retail pharmacies. Data elements A. and B. indicate that PDPs and regional PPOs must report data by state, while MA-PD plans must report by service area. A number of PDPs and regional PPOs serve multi-state regions.	Recommend that PDPs and regional PPOs be required to report by service area (including multi-state service areas), consistent with the approach proposed for MA-PD plans, or that CMS explain the rationale for requiring PDPs and regional PPOs to report by state.	Do not accept	Data collection is consistent with CMS policy.	
AHIP; Unnamed organization.	Appeals	Data Element B. requires Part D plan sponsors to enter into HPMS the number of requests for redeterminations "dismissed" by the plan.	Recommend that CMS include examples of the circumstances under which Part D plan sponsors may dismiss a request for a redetermination drawn from Chapter 18 of the Prescription Drug Benefit Manual.	Accept	This element will be deleted as a Plan rarely dismisses a request for a redetermination. It will be clarified that data element A, number of requests for determinations should reflect the total number of requests.	edit
BCBS of FL	Appeals	Does data element A include both standard and expedited appeals?		Clarify	Yes, both standard and expedited appeals should be included.	tech specs
Medco; Unnamed organization.	Appeals	Elements deleted from data collection related to IRE redeterminations.	Confirm plans do not have to report on appeals submitted for IRE or decisions made by the IRE, and clarify how these data will be obtained by CMS.	Clarify	It is correct that plans do not have to report on IRE redeterminations. CMS will obtains these data directly from the IRE.	
Medco	Coverage Determinations and Exceptions	Element G	Provide guidance for distinguishing a prior authorization from a prior authorization exception. Clarify the reason for grouping quantity limit exceptions in with all other exceptions.	Clarify	A coverage determination is made when plan applies approved prior authorization (PA) criteria to determine if a drug will be covered. An exception is when the plan decides if an exception to the PA criteria is available in order to cover the drug. CMS has combined the quantity limit exception with all other exceptions because Sponsors were inconsistently reporting data when exceptions were separated by UM tools.	tech specs

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
SilverScript Insurance Company/SSLLC, Medco	Coverage Determinations and Exceptions	Addition of data Element A, total number of pharmacy transactions.	Clarify the term "pharmacy transactions", if it includes rejected claims, and if it is equivalent to the number of pharmacy claims. Number of pharmacy claims is already reported in Generic Drug Utilization.	Clarify	It is important to note that one pharmacy claim may be associated with more than one pharmacy transaction. Pharmacy transactions encompass all transactions, including rejections. Pharmacy transactions is not equivalent to the number of pharmacy claims, and this data element is not duplicative to data reported for Generic Drug Utilization.	
BCBS of FL, AHIP	Coverage Determinations and Exceptions	Element E and F	Clarify non-prior authorization coverage determinations and provide examples of such coverage determinations. Clarify if non-PA includes step therapy and quantity limits.	Clarify	These elements will be deleted, as these are potentially reported in other data elements (G-L)	edit
BCBS of FL	Coverage Determinations and Exceptions	Element G	Clarify if data element G is a rollup of C and E.	Clarify	No, G is not a rollup of C and E. C and E relate to coverage determinations based on UM tools. G relates to the number of exceptions requested to UM tools.	tech specs
Medco	Coverage Determinations and Exceptions	Modified data element B, the number of pharmacy transactions rejected due to formulary restrictions, including non-formulary status, prior authorization requirements, step therapy, and quantity limits (QL). Rejections due to early refills should be excluded.	Clarify the reason for rolling previous separate data elements for numbers of step therapy rejects, prior authorization rejects and quantity limit rejects.	Clarify	Sponsors were inconsistently reporting data when exceptions related to utilization management (UM) tools were reported via separate data elements. In order to improve data consistency and accuracy, as well as reduce reporting burden, the number of pharmacy transactions rejected has been combined into one element.	
Medco	Coverage Determinations and Exceptions	Element E, the total number of non-prior authorization coverage determinations requested	Clarify non-prior authorization coverage determinations, and would coverage determinations for non-Medicare Part D drugs, requests for Out of Network coverage, direct claim coverage determinations (including claims with missing information, prior authorization required, eligibility determinations, etc.) be included?	Clarify	Data element E will be deleted.	edit
Medco	Coverage Determinations and Exceptions	Element E (the total number of non-prior authorization coverage determinations requested in the time period.).	Clarify if quantity limit and/or step therapy coverage determinations should be included in this category.	Clarify	Data element E will be deleted.	edit
Medco	Coverage Determinations and Exceptions	Element C (the total number of prior authorizations.) and Element G (the total number of exceptions requested related to the Plan's utilization management tools, e.g. prior authorization, quantity limits, or step therapy requirements)	Clarify the difference between data elements C and G.	Clarify	These two elements distinguish coverage determinations (element C) from the exceptions process (element G).	tech specs

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
BCBS of FL, SilverScript Insurance Company/SSLLC	Drug Benefit Analyses	Quarterly reporting timeframes	Clarify how to report LIS members whose status can change within the quarterly period. Confirm that quarterly reports no longer require monthly breakdowns of reported items.	No Action	Document lists quarterly reporting periods, and that data are to be reported as of the last day of the quarter.	
HealthPartners	Employer/ Union Sponsored Group Health Plan Sponsors	Data element D - employer DBA name is sometimes difficult to obtain.	Delete this element.	Do not accept	Plans should exert a reasonable effort to get this information.	
HealthPartners	Employer/ Union Sponsored Group Health Plan Sponsors	Alignment with Part C reporting section.	Align fields in this report with the corresponding Part C report.	Accept	CMS will ensure consistency in data format for Parts C and D reporting. File format, and other technical specifications are outside the scope of the Part D reporting requirements document, and will be provided elsewhere.	tech specs
BCBSA	Enrollment	Quarterly reporting timeframes	Due to plans' burden of reporting (Q1 and Q4 includes open enrollment periods), revise to semiannual reporting periods, or extend due dates if quarterly periods are retained.	Do not accept	Quarterly collection is necessary for CMS monitoring. Reporting deadlines are 45 days after the end of the reporting period.	
BCBS of FL	Enrollment	Data element A, the total number of enrollment requests received	Clarify if only those applications received by the plan (i.e. hardcopy, website, fax, OEC, etc) should be included, and does not include CMS generated enrollments (received via TRR only). Clarify if it includes individual and group (EGWP).	Clarify	Include all plan submitted enrollments that are a result of an enrollment request. The enrollments include both individual and Group (EGWP). Plans should not include enrollments where the enrollment transaction is created and submitted by CMS.	tech specs
BCBS of FL	Enrollment	Data element B, the number of enrollment requests denied due to the Plan's determination of the ineligibility of the individual to elect the plan	Confirm if this references the eligibility check performed via the BEQ, if so, expand the definition with additional examples.	Clarify	Include all denials made by the plan. Refer to the PDP Guidance on Enrollment and Eligibility or Medicare Managed Care Manual Chapter 2- Medicare Advantage Enrollment Some examples of plan denials are that the beneficiary does not have a valid enrollment period, resides outside of the service area, or does not meet the requirements necessary to enroll in a SNP.	tech specs
BCBS of FL	Enrollment	Data element C, the number of enrollment requests denied due to the individual not providing information to complete the enrollment request within established timeframes.	Confirm this refers to enrollment requests requiring any additional beneficiary information that are denied after 21 days.	Clarify	CMS confirms this refers to enrollment requests requiring any additional beneficiary information that are denied after 21 days, in the current guidance.	tech specs
BCBS of FL	Enrollment	Confirm that data elements B-D are subsets of data element A.		Clarify	Data elements B-D include the statement, "Of the total". Will clarify further that these are subsets of A.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
Medco	Enrollment	Quarterly reporting timeframes	Point in time reporting may not give a true picture of enrollment, not all actions on an enrollment record may complete within the time period. CMS may receive incomplete information, reducing report's value. For example, an incomplete request received on the last day of the reporting period, but completed in the following reporting period would not be reported in either quarter's report.	Clarify	The report should include the outcome of all enrollment requests that are received during the quarter. There is sufficient time between the end of the reporting period and the data due date. For example, there is more than 21 days, so there is sufficient time to report the "denials" do to incomplete applications.	tech specs
Ovations/United Health Group	Enrollment	Data elements E-J	Clarify the term, enrollment transactions submitted. Is the intention to evaluate processing of applications and beneficiaries' understanding of eligibility for participation; if so, this would presume that just new enrollments would be reported--accretions with codes 60, 61 and 62. Or, would CMS include code 71, Plan Benefit Package (PBP) changes?	Clarify	Plan should include all enrollments (60, 61, 62 and 71 transactions).	edit
HealthPartners	Enrollment	2010 Reporting Requirements require Sponsors to track the frequency of use of SEPs by product and provide to CMS quarterly. We maintain the documentation and evidence for each SEP in each beneficiary's case file, but we do not currently aggregate and track this information. In order to implement the reporting requirements as written, Part D Sponsors will continue to send these enrollments/ disenrollments as general "other" SEP, but separately track the actual SEP granted. This will require us to develop new system functionality track separately or administrative resources to track manually.	Recommend CMS create unique codes from each SEP situation and require Part D Sponsors top transit the unique code at the time of enrollment.	Do not accept	Plans should pay special attention to SEP definitions , which group several SEPs into a single data element. CMS will consider developing submission codes for the SEPs in the future, as suggested.	
HealthPartners	Enrollment	Clarification needed.	Clarify which plans this report applies to (PDPs, MA-PDs, Individual or EGWP).	Clarify	This report applies to all plans	
Kaiser	Enrollment	CMS is requesting that plans provide information about enrollment requests and transactions.	Clarify that the enrollment requests that need to be reported relate only to new enrollments, rather than new enrollments and PBP changes; and that the data elements to be reported in this Section only relate to enrollment requests and not disenrollment requests.	Clarify	Plan should include all enrollments (60, 61, 62 and 71 transactions). Disenrollments are not included in these data elements.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
SilverScript Insurance Company/SSLLC	General	A comment was received regarding the fact that for several reporting elements, CMS has changed the due date for the quarterly report from the end of the month to the middle of the month. The reporting process for most Part D sponsors involves many steps, and the timelines are already very tight. This is because much of the data resides at the PBM, where the data first has to be collected by the relevant business or operational area, then it has to be compiled in the appropriate format and at the appropriate entity level for many clients, and then it has to be sent to the Part D sponsor in sufficient time for the Part D sponsor to verify the data and submit it to CMS. Bringing the submission date up by two weeks will put a significant strain not only on resources, but on an already complex process and tight timeline. The result is likely to be more errors or incomplete or compromised data.	Recommend that CMS leave the due dates for the quarterly reports unchanged to allow sufficient time to collect and report the data required.	Do not accept	Deadlines will remain as posted. CMS has adjusted reporting periods to cumulative YTD periods whenever appropriate to accommodate instances where reports may require updating subsequent to the first dataset reported to CMS.	
SilverScript Insurance Company/SSLLC	Fraud, Waste and Abuse Compliance Programs	In some cases FWA incidents may also be the basis for a grievance, should items reported in this section be excluded from grievance reporting or be reported under Grievances as well if the incident gave rise to a grievance.	Clarify that all potential fraud, waste and abuse incidents be reported in this Section, even if some of the same incidents give rise to a grievance that is reported in the Grievance section	Clarify	Data element F. will be revised to add clarification to include incidents that give rise to grievances.	edit
BCBSA	Fraud, Waste and Abuse Compliance Programs	Self-reporting is not required under any provision established in law. Object to CMS efforts to adopt mandatory self-reporting via RR. Mandatory self-reporting is not required for providers in traditional Medicare, places undue risk on plans. (Letter to Kuhn, 2007)	Oppose mandatory self-reporting of violations, CMS should withdraw reporting requirements involving mandatory self-reporting.	Do not accept	Per 423.504, plans will voluntarily report aggregate data for this section. Language will be modified to clarify this.	edit
BCBSA	Fraud, Waste and Abuse Compliance Programs	Significant concerns, essentially requires Plans to self-report incidents of fraud and abuse, as defined via vague definitions and categories. CMS lacks authority to adopt a self-reporting requirement for MA and Part D programs. CMS cannot adopt such a requirement through reporting requirements that are not subject to rulemaking procedures.	Eliminate this reporting section.	Do not accept	Per 423.504, plans will voluntarily report aggregate data for this section. Language will be modified to clarify this.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
BCBSA	Fraud, Waste and Abuse Compliance Programs	Data elements are vague and will force plans to launch resource-intensive investigations to respond to allegations and complaints, impose on Plans administrative burdens and legal liability inappropriately. Definitions of fraud and abuse incidents are vague and require Plans make judgments (e.g. intentional action or mistake). Judgments require investigations, which may not be appropriate action given alleged incident or complaint. Plans could increase their liability based on classification requirement, unreasonable business risk for CMS to impose on sponsors. Arbitrary nature of judgments eliminate any data consistency, prevent Plan comparisons - therefore little benefit to CMS and Plans, but significant cost and liabilities.	Eliminate this reporting section.	Do not accept	Per 423.504, plans will voluntarily report aggregate data for this section. Language will be modified to clarify this.	edit
Horizon BCBS NJ	Fraud, Waste and Abuse Compliance Programs	Large volume of the inquiries received by Plan come from Medic, and Plan does not have all details.	No specific changes recommended.	No Action		
Medco	Fraud, Waste and Abuse Compliance Programs	For data element A, the number of potential fraud and abuse incidents related to inappropriate billing, would all types of inappropriate billing by pharmacies provided in Chapter 9 be counted in this data element? Under a separate category in Chapter 9, there are additional examples of fraud, such as prescription drug shorting and prescription forging and altering, that might also be considered inappropriate billing by a pharmacy. For example, a pharmacy may short a prescription and then bill for the fully-prescribed amount.	Clarify if the plan should count only those cases that fall under the "inappropriate billing practices" in Chapter 9 in this category or also include other examples involving fraudulent practices by pharmacies in Chapter 9.	Clarify	Data element A will be changed to include pharmacy.	edit
Medco	Fraud, Waste and Abuse Compliance Programs	Data element A	Clarify if cases of direct billing by the pharmacy to the plan sponsor should be included in the category.	Clarify	Data element A will be changed to include pharmacy.	edit
Medco	Fraud, Waste and Abuse Compliance Programs	Data element B, the number of potential fraud and abuse incidents related to providing false information, is unclear.	Provide an example of the type of fraud or abuse that would fall into this category.	No Action	This comment is out of the scope of this RR document. Definitions are provided in Chapter 9 of the Prescription Drug Benefit Manual.	

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
Medco	Fraud, Waste and Abuse Compliance Programs	Data element G, of the total number of potential fraud and abuse incidents, the number identified through internal efforts, is unclear.	Confirm that data mining would fall into this category. Clarify if hotline calls from employees or members would be included in this category.	No Action	This comment is out of the scope of this RR document. Definitions are provided in Chapter 9 of the Prescription Drug Benefit Manual.	
Medco	Fraud, Waste and Abuse Compliance Programs	Data element H, of the total number of potential fraud and abuse incidents, the number of incidents received from external sources, is unclear.	Confirm that incidents identified through requests for information from the MEDIC or law enforcement would fall into this category.	No Action	This comment is out of the scope of this RR document. Definitions are provided in Chapter 9 of the Prescription Drug Benefit Manual.	
Medco	Fraud, Waste and Abuse Compliance Programs	Does data element F, the number of incidents/complaints reported, equal data element I, the number of inquiries initiated by the Sponsor as a result of potential fraud and abuse incidents.	Confirm.	No Action	This comment is out of the scope of this RR document. Definitions are provided in Chapter 9 of the Prescription Drug Benefit Manual.	
Medco	Fraud, Waste and Abuse Compliance Programs	Does the sum of data elements G and H equal to data element I?	Confirm.	No Action	This comment is out of the scope of this RR document. Definitions are provided in Chapter 9 of the Prescription Drug Benefit Manual.	
Medco	Fraud, Waste and Abuse Compliance Programs	Data element J, the number of corrective actions initiated by the Sponsor as a result of potential fraud and abuse incidents, is unclear.	Confirm if letters to prescribers or patients regarding a drug abuse incident, or termination of a pharmacy contract be included in this category. Provide additional examples of corrective actions that would be counted in this element.	No Action	This comment is out of the scope of this RR document. Definitions are provided in Chapter 9 of the Prescription Drug Benefit Manual.	
Medco	Fraud, Waste and Abuse Compliance Programs	Data element J, the number of corrective actions initiated by the Sponsor as a result of potential fraud and abuse incidents, is unclear.	Confirm if an external referral to CMS or law enforcement should be considered a corrective action and included in element J.	No Action	This comment is out of the scope of this RR document. Definitions are provided in Chapter 9 of the Prescription Drug Benefit Manual.	
Medco	Fraud, Waste and Abuse Compliance Programs	In what element would plans utilize to report the number of incidents identified for prescribers who are on the OIG/GSA exclusion list and have written claims for members? Would plans count each claim that was submitted that was written by the excluded individual, or would the plan count each physician identified as a single case?	Clarify.	Clarify	Language will be added to data element F to include the OIG Exclusion List as an example.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
Ovations/United Health Group	Fraud, Waste and Abuse Compliance Programs	Clarify the scope of the proposed reporting section. While the definitions align with commonly agreed to standards such as 'intentional deception', the data elements indicate the reporting should be inclusive of all potential fraud and abuse incidents. Upon initial review, all proposed reporting categories required some level of review or initial investigation to identify the case as a potential fraud versus a miscategorized complaint or report.	Clarify.	Clarify	Expectation is that reporting will occur post reasonable inquiry to distinguish between general complaint and reportable event (i.e. potential Fraud, Waste or Abuse)	tech specs
Ovations/United Health Group	Fraud, Waste and Abuse Compliance Programs	Clarify the inclusion of broker or agent related complaints since separate mechanisms and oversight processes exist to monitor and review potential marketing misrepresentation incidents. Clarify if incidents received via the CMS Complaint Tracking Module (CTM) should be included in this reporting section, as incidents received from external sources.	Reconsider requiring plans to report broker agent related complaints to eliminate duplicative reporting.	Clarify	Data element H will be revised to clarify that CTM complaints should be included. Data element F will be revised to clarify that broker agent complaints should be included.	edit
Kaiser	Fraud, Waste and Abuse Compliance Programs	CMS is requiring that Part D sponsors report information related to their anti-fraud, waste and abuse activities.	Clarify if reported incidents should relate specifically to Part D members (as opposed to the general population).	No Action	Incidents are limited to those incidents related to Part D enrollees, per Part D reporting requirements.	
BCBSA	General	Proposed changes are not feasible for Plans to identify, collect, and report.	Eliminate or modify data elements to information Plans have ready access, and not unreasonable in cost to collect.	Accept	CMS has deleted elements that are duplicative to other reporting, and added language to clarify for Sponsors that these data will be used in other analyses.	
AHIP	General	Most sections of the draft CY 2010 Medicare Part D Reporting Requirements continue to require Part D sponsors to enter data elements directly into HPMS. The process of manually entering these data is time and labor intensive, and organizations with multiple contracts may need to separately key in the same data several times, heightening the potential for errors.	Recommend CMS establish an automated or upload process for submission of data to satisfy the reporting requirements.	Do not accept	CMS will continue to evaluate procedures for uploading plan-reported data, however errors and technical issues exist with current reporting sections with data uploads. Regardless of the data submission process, CMS reiterates the need for Sponsors' QA of data.	

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
SilverScript Insurance Company/SSLLC	Generic Drug Utilization	A commenter indicated that CMS has deleted the sentence stating "First DataBank or Medispan generic drug classifications will be used to identify generic drugs." Since these databases are the ones generally used for this purpose, it was not clear to the commenter if this deletion was to allow other sources to be used as well or to no longer allow these databases. The commenter requests clarification whether Part D sponsors may continue to use MediSpan and First DataBank to define generics for purposes of this reporting section.	The commenter recommends that CMS make clear that Part D sponsors may continue to use these databases for this purpose, even though the commenter understands that the technical definition of a "generic" drug for LIS and catastrophic cost sharing may be different.	Clarify	Clarification will be added that these databases may be used, and to reiterate the definition of a generic drug.	edit
Unspecified Private Industry - Drug	Generic Drug Utilization	Clarification needed.	Clarify how non-drug generic items (insulin syringes, alcohol swabs & gauze pads) to be handled.	Clarify	It will be clarified that non-drug items should be excluded from these data.	edit
BCBSA	Grievances	Data elements are vague, redundant. Grievances by LIS/nonLIS do not have meaningful distinction. Categorization of grievances is arbitrary, and lacks analytical basis for Plan comparisons or evaluations.	Eliminate # of distinct beneficiaries filing a grievance. Eliminate categories of grievances, or provide greater specificity to categories to make collection and analysis more meaningful.	Do not accept	Monitoring of Sponsors' grievance processing requires consideration of the number of distinct beneficiaries filing grievances, and the types of grievances commonly received by Sponsors. CMS has revised the grievance categories to be more broad in response to Sponsors' feedback that previous categories were too specific, and caused inconsistencies in data reporting.	
BCBS of FL	Grievances	Is fraud/waste/abuse data reported here a subset of new section, Fraud, Waste and Abuse Compliance Programs		Accept	The fraud, waste, and abuse grievance category will be deleted as these are already included in the data collected in the FWA reporting section. For purposes of the total grievance count, Sponsors should include these in the "Other" category.	edit
BCBS of FL	Grievances	Grievance categories	Provide definitions for each category.	Do not accept	Core categories are listed, and CMS believes they are intentionally broad for Sponsors to be able to categorize grievances.	
BCBS of FL	Grievances	Grievance categories	What should be included in category of Other?	Clarify	Grievances which the Sponsor cannot categorize in one of the other core categories.	

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
HealthPartners	Grievances	Inconsistency in reporting between Part C and Part D elements makes it difficult to program system data pulls since we must ask for reports from the same reporting database using different data element definitions. EX. Part C Grievance section, plans are asked to report from "only completed grievances. Part D reporting Grievance and Appeals sections ask sponsors to report data related to grievances/ appeals received.	Recommend Part C and Part D data element definitions be common.	Do not accept	This comment is out of the scope of this RR document.	
Unspecified Health Care Industry	Grievances	The categories for 2010 have been drastically reduced (currently we report on 11 various categories) in 2010 it drops to 4 main categories of which one states: Coverage determinations/Exceptions and Appeals process (e.g. untimely decisions). The other 3 categories are 1. Fraud, waste or abuse 2. Enrollment, plan benefits, or pharmacy access, and 3. Customer Service. This section seems to contradict itself in stating that we are not to include 'coverage determinations' as a grievance but then this section includes turn around times and a category to report on. We are unclear of what should be reported in this category.	Clarify if coverage determinations/ exceptions and appeals filed under the grievance section only for those where the plan did not make a decision timely.	Clarify	No, Plans should not automatically include the number of untimely coverage decisions in this section. They should include any grievances filed by beneficiaries because they did not receive timely decisions. This element will be revised to clarify this.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
AHIP	Grievances	Grievances received v. completed grievances. The introductory language in the first paragraph under this section indicates that "Part D Sponsors will be responsible for reporting data related to grievances received." However, the recently issued final Medicare Part C Reporting Requirements indicate under the corresponding section, Section 5: Grievances (see Notes section), that only "completed grievances (plan notified enrollee of its decision) during the reporting period should be included." If retained, the discrepancy between the Part D and Part C requirements would make reporting significantly more complex for Medicare Advantage organizations participating in both programs, and it is does not appear that the differing requirements would provide more useful data.	Recommend that CMS make this aspect of the data reporting requirement consistent for the Part C and Part D programs.	Do not accept	The Part D reporting section accurately reflects the collection of all grievances. This comment is outside the scope of the Part D RR document.	
AHIP	Grievances	Due date for data submission. The proposed CY 2010 Reporting Requirements shorten the due date for uploading grievance data following the end of the reporting period (calendar quarter) from 60 days to 45 days. The new deadlines are likely to be problematic in some circumstances, because the shorter data submission deadline could fall too early for complete data to be available. For example, if an enrollee submits a grievance at the end of a reporting period and an allowable 14-day extension of the timeframe for notification of a determination applies, the Part D plan sponsor would be required to notify the enrollee by the 44th day following the close of the reporting period. However, the deadline for uploading the data in HPMS would be the 45th day.	Recommend that CMS retain the reporting deadlines included in the CY 2009 Part D Reporting Requirements. If CMS does not adopt this recommendation, we recommend that the agency provide an explanation of the manner in which a circumstance such as the example above would be addressed.	Do not accept	The reporting deadlines will not be revised. Plans may elect to report data on the reporting deadline in order to capture the most complete dataset.	

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
AHIP	Grievances	Non-LIS beneficiaries. The chart titled, "Summary of grievance data," calls for Part D plan sponsors to report the number of grievances filed by LIS beneficiaries and the number filed by non-LIS beneficiaries, as well as the number of distinct LIS beneficiaries filing a grievance and the number of distinct non-LIS beneficiaries filing a grievance. It appears that the category of "non-LIS beneficiaries" in each case includes all beneficiaries who are not classified as "LIS beneficiaries."	Clarify the term and provide examples of "non-LIS beneficiaries."	Clarify	The term "non-LIS" beneficiaries refers to beneficiaries that do not receive low-income subsidy (LIS).	edit
SilverScript Insurance Company/SSLLC	Long-Term Care (LTC) Utilization	A commenter indicated that the due dates for these reports are December 31 and June 30 respectively and noted that these dates could be interpreted as being current year or following year.	The commenter recommends that CMS specify the year as part of the due date requirement to avoid any confusion.	Accept	A statement will be added to the introduction of the RR document to clarify that reporting deadlines may occur in the following calendar year.	edit
SilverScript Insurance Company/SSLLC	Long-Term Care (LTC) Utilization	A commenter has requested clarification on how MA-PDs are suppose to report the total number of network LTC pharmacies licensed to serve in the service area. The commenter noted that the that PDPs and regional PPOs must report by state, but does not specify how this must be done for MA-PDs.	The commenter recommends that CMS clarify how Data Element A is to be reported for MA-PD plans, as it has for PDPs and regional PPOs.	Accept	CMS will provide clarification that MA-PDs will report by service area.	edit
BCBS of FL	Long-Term Care (LTC) Utilization	Is data element A the total # of LTC pharmacies licensed in general in the service area, or the total # of pharmacies contracted in the service area?		Clarify	Data element A is the # LTC pharmacies contracted in the service area.	edit
BCBS of FL	Long-Term Care (LTC) Utilization	Data elements A and B - Pharmacies are licensed in states. What if service areas cross state lines?		Clarify	Depending on the organization type, the contract will report the # of pharmacies in the state or in the service area. If reporting # of pharmacies by state, a pharmacy licensed in more than one state will be reported by each state it is licensed.	edit/tech specs
BCBS of FL	Long-Term Care (LTC) Utilization	Data elements D and E - define specifically cost. Does it include tax, dispensing fee, member pay?		Clarify	CMS will provide clarification for calculating prescription costs.	edit/tech specs
HealthPartners	Long-Term Care (LTC) Utilization	Clarification needed.	Recommend that CMS provide a clear definition of what is considered a LTC pharmacy.	Clarify	CMS will provide clarification.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
HealthPartners	Long-Term Care (LTC) Utilization	Clarification needed.	Clarify what happens if a pharmacy serves both a LTC facility and the general public through a retail operation - would that pharmacy be counted in this report or not?	Clarify	If possible, pharmacies that serve as LTC and retail should be counted in both data elements A and B, and then have their claims/utilization reported separately according to business lines. When this is not possible, Plans should count the pharmacy as a LTC pharmacy (data element A) and report all claims as LTC utilization (data element D).	edit/tech specs
Kaiser	Long-Term Care (LTC) Utilization	We are concerned that a direct comparison of the number of prescriptions may also be misleading unless the reporting is normalized to a standard days supply (e.g. 30 day prescription equivalents). For example, a plan that has a high number of mail order prescriptions that are dispensed in 90 day supply increments will appear to have a higher cost per prescription in comparison with an LTC pharmacy that dispenses prescriptions in 30 day supply increments.	Recommend that CMS standardize the prescription days supply for this report in order to make the comparison more equitable; clarify the term "licensed" for this report. This term is used in some data elements (e.g. A and D) and is not used in other data elements (B and E).	Clarify	The term licensed will be deleted. Non-LTC will be revised to state retail pharmacies. Clarification will be made that LTC prescriptions should be reported using 31-day equivalents, and retail prescriptions should be reported using 30-day equivalents.	edit/tech specs

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
Kaiser	Long-Term Care (LTC) Utilization	In addition to the number and cost of all formulary and all non-formulary medications for each contracted LTC pharmacy, CMS is asking plans to report the aggregate number and cost of all formulary and all non-formulary medications for non-LTC pharmacies. CMS will compare LTC and non-LTC data to determine if the LTC network pharmacies' rebates conflict with the plan's formularies or drug utilization management programs. We are concerned that a direct comparison of LTC vs. non-LTC data may be misleading because of the many other variables besides rebate incentives that can contribute to the volume and cost of prescriptions. For example, LTC residents typically receive a greater number of prescriptions than non-LTC residents and therefore will have a higher number of prescriptions and prescription costs per beneficiary than non-LTC residents. Similarly, the contracted prices may vary between LTC and non-LTC pharmacies which can also skew the data towards higher prescription costs for LTC pharmacies.	Recommend comparison of data for just the LTC pharmacies and subsequent evaluation of outliers may be a possible alternative data evaluation method.	Accept	Data elements B and E will be deleted.	edit
AHIP	Long-Term Care (LTC) Utilization	Data Element B. requires Part D plan sponsors to enter into HPMS the total number of network "non-LTC pharmacies" in the plan's service area, and data element E. calls for other data for "non-LTC pharmacies." It is our understanding that the category of "non-LTC pharmacies" may be unclear in some circumstances. For example, it is our understanding that some pharmacies may serve as both retail and LTC pharmacies.	Recommend CMS state how data for pharmacies that engage in more than one type of pharmacy business should be reported.	Clarify	If possible, pharmacies that serve as LTC and retail should be counted in both data elements A and B, and then have their claims/utilization reported separately according to business lines. When this is not possible, Plans should count the pharmacy as a LTC pharmacy (data element A) and report all claims as LTC utilization (data element D).	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
AHIP	Long-Term Care (LTC) Utilization	Data Element B. requires Part D plan sponsors to enter into HPMS the total number of network "non-LTC pharmacies" in the plan's service area, and data element E. calls for other data for "non-LTC pharmacies." It is our understanding that the category of "non-LTC pharmacies" may be unclear in some circumstances. For example, it is our understanding that some pharmacies may serve as both retail and LTC pharmacies.	Recommend CMS explain the term "non-LTC pharmacies," including providing examples of types of pharmacies in this category.	Accept	Non-LTC will be revised to state retail pharmacies.	edit
Medco	MTM Programs	Section II - elements L, M, N, O, P, Q, R, S and T, should be eliminated because the current medical system does not provide a complete feedback loop to allow for accurate reporting.	Recommendations made to patients and providers may not necessarily be implemented or measurable as a direct result of MTM. For example, if there is a MTM recommendation to change drug therapy, it may not happen immediately. A physician may need to examine the patient and then make the change which will take time. The rules about what are direct or indirect results are onerous and the information will not be meaningful. CMS should consider high level measures of MTM impact such as overall Cost and Rx utilization as is currently in place and summary metrics on compliance.	Accept	In Section II, CMS will remove the word "direct" in data elements R and S. Additionally, CMS will revise data elements O - T to be combined into one data element (O). Elements L - T will not be deleted; CMS expects sponsors have the capability to retain and report outcomes.	edit
Ovations/United Health Group	MTM Programs	Section II, elements O - T, the commenter notes the requirement to measure and report the change(s) in therapy directly resulting from MTM interventions may not be practicable. The commenter sites that there are many reasons a member may change therapy. Unless a provider specifically reports the reason for the change, it would not be possible to determine whether a change was made due to the MTM intervention or if the change was made for other reasons (e.g., due to a dispensing pharmacist or prescriber). Additionally, the commenter requests clarification on how close in time would a change need to be in order to be considered a direct result of the MTM program?	The commenter recommends that CMS request plans report only the changes in medication therapy and not to which program the changes are attributable. In the alternative, the commenter recommends that CMS work with the industry to develop criteria for measuring and reporting the effectiveness of MTM programs.	Accept	In Section II, CMS will remove the word "direct" in data elements R and S.	edit
SilverScript Insurance Company/SSLLC	MTM Programs	Section II - file format	Confirm the file layout remains tab delimited. The commenter recommends that format should remain the same as the existing report format.	Clarify	Yes, the file will continue to be a tab delimited layout.	tech specs

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
SilverScript Insurance Company/SSLLC	MTM Programs	Section II, elements R and S - many MTM programs do not involve therapeutic or generic substitution.	Clarify if zero will be an accepted value.	Clarify	In Section II, CMS will combine data elements O - T into one data element (O). Zero values will be an accepted value for this section.	edit/tech specs
BCBSA	MTM Programs	Data element K: Average amount of time to complete annual comprehensive medication per MTMP enrollee (hh:mm) requires manual, labor and cost intensive effort. The value to CMS is questioned as it does not indicate quality of review, and cannot be used for accurate comparisons of Plans activities.	Eliminate this data element.	Accept	This data element will be deleted.	edit
BCBSA	MTM Programs	Section II, data element N: # provider interventions is too vague to be reliable or enable Plan comparisons, does not justify labor/cost burden.	Eliminate this data element.	Do not accept	For consistency with 2010 Call letter, this element will be revised to state prescriber instead of provider.	edit
BCBSA	MTM Programs	Section II, data element N: # provider interventions	Clarify what constitutes provider intervention - general provider interventions (educational mailings) or member/patient specific interventions?	Clarify	For element N in Section II, CMS will change this element to prescriber interventions instead of provider interventions. Sponsors should refer to pages 71 - 73 of the 2010 Call Letter for a detailed explanation of appropriate interventions.	edit
BCBSA	MTM Programs	Section II, elements O - T require medical record review - unreasonable for Plans. PDPs do not have access to medical records.	Modify to collect only information Plans can collect and confirm. Revise to biannual collection, from proposed quarterly.	Do not accept	Data elements O - T will be revised into one data element (O). CMS notes that medical records are not the only source of outcomes reporting.	edit
Horizon BCBS NJ	MTM Programs	Proposed changes will require costly IT funding for plans.	No specific changes recommended.	No Action		
BCBS of FL	MTM Programs	Define terms enrolled and enrollment. The 2010 call letter uses the term participating.		No Action	These terms are consistent with the 2010 call letter.	
BCBS of FL	MTM Programs	Does data element A, the total number of beneficiaries identified to be eligible for, and were automatically enrolled in, the MTMP, include members they have been unable to make direct contact, e.g. beneficiaries did not opt out, they are unavailable.		Clarify	Yes, sponsors should include members that they have been unable to make direct contact in data element A. These members should not be included in data elements B - F and elements I - K. Sponsors are also still expected to do the targeted medical review and follow up with the physician.	tech specs
BCBS of FL	MTM Programs	Confirm that data elements B is a subset of A.		Clarify	Yes, data element B is a subset of A.	tech specs
BCBS of FL	MTM Programs	Confirm that data elements C-F are subsets of B.		Clarify	Yes, data elements C - F are subsets of B.	tech specs
BCBS of FL	MTM Programs	Confirm that data element G is a subset of A.	If not, revise the first sentence to ensure Plans exclude opt out members	Clarify	Yes, data element G is a subset of A.	tech specs

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
BCBS of FL	MTM Programs	Confirm that data element H is a subset of A.	If not, revise the first sentence to ensure Plans exclude members who opted out	Clarify	Yes, data element H is a subset of A.	tech specs
BCBS of FL	MTM Programs	Confirm that data element I is a subset of A.	If not, revise the first sentence to ensure Plans exclude members who opted out	Clarify	Yes, data element I is a subset of A.	tech specs
BCBS of FL	MTM Programs	Clarify term "offered" - contact by letter, call?	Clarify	Clarify	Part D Sponsors should determine the method of outreach to the beneficiaries. CMS expects that sponsors will use multiple methods of outreach.	
BCBS of FL	MTM Programs	Confirm that data element J is a subset of A.	If not, revise the first sentence to ensure Plans exclude members who opted out	Clarify	Data element J is a subset of element I and data element I is a subset of element A.	tech specs
BCBS of FL	MTM Programs	Data element K - is it a subset of A?	If not, revise the first sentence to ensure Plans exclude members who opted out	Clarify	No, data element K is not a subset of A. Data element K is a measure of time.	tech specs
BCBS of FL	MTM Programs	For data elements I-K, what constitutes a medication review?	What are the requirements?	Clarify	For an overview of what constitutes a medical review, sponsors should refer directly to the 2010 call letter and 2010 Submission Guidance.	
BCBS of FL	MTM Programs	For Section II, data element H.	Recommend this is modified to "date of MTMP participation" or "date of MTMP enrolled participation.	Do not accept	No, data element H refers to beneficiaries enrolled in the MTMP.	
BCBS of FL	MTM Programs	For Section II, data elements O-T, define direct result.		Accept	CMS will remove the word "direct" in data elements R and S. Additionally, CMS will revise data elements O - T to be combined into one data element (O).	edit
HealthPartners	MTM Programs	The 2010 Call Letter stipulates that Part D Sponsors offer the MTMP to all eligible beneficiaries. If this proposed change is adopted, then elements A (# eligible) and I (# offered) would be duplicative since eligible will equal offered.	Request one of the two duplicate elements be deleted.	Do not accept	Data elements A and I are important and distinct. They may not always be equal. Data element I is necessary as it serves as denominator for evaluating data element J.	

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
Kaiser	MTM Programs	CMS is proposing to institute a new requirement that enrollees of MTM programs receive a Comprehensive Medication Review (CMR). We are seeking guidance on whether CMS expects that this review will be completed annually or whether it is a one-time offering to new MTM enrollees. We recommend that an enrollee receive the CMR once while enrolled in the program in consecutive years, to be supplemented by ongoing quarterly medication reviews. The plan should then have the flexibility to determine the best course of intervention for an individual patient. Some patients may require a CMR annually or more frequently, while others may require CMR less frequently than annually. We believe that the initial CMR and subsequent quarterly reviews establish a sufficient baseline of care and that plans should have flexibility beyond this baseline to do more targeted interventions with enrollees. CMS is proposing that the enrollment process for MTM be “opt out” only.	Recommend plans be allowed to put enrollees in “inactive” status based on a defined number of attempted contacts without enrollee response.	Do not accept	The call letter has indicated that the Comprehensive Medical Review (CMR) must be completed at least annually. The recommendation to allow plans to put enrollees in an "inactive" status based on a defined number of attempted contacts without enrollee response is out of the scope of this document.	
Kaiser	MTM Programs	Field I.I: Number of enrollees offered Comprehensive Medication Review (CMR).	Clarify this field will always be 100%, since all members will be offered the CMR.	Clarify	CMS expects that element I will be 100%, but there may be instances where this may not be the case.	tech specs
Kaiser	MTM Programs	Field I.J: Number who received CMR.	Clarify this number can be less than 100% (for examples enrollees who never respond to offer of CMR or those who decline CMR).	Clarify	Yes, data element J may be less than 100%. Some beneficiaries may decline the Comprehensive Medical Review.	tech specs
Kaiser	MTM Programs	Field II.H: Date of MTMP Enrollment.	Clarify that since enrollment is “opt out” only, this would be the date that plans invite the enrollee to join the program.	Clarify	Yes, since enrollment is opt out only, data element H is the date that the plan invites the enrollee to join the program.	tech specs
Kaiser	MTM Programs	Field II.K: Received annual CMR.	Clarify this is a “yes” or “no” field.	Clarify	Data element K is a yes or no field.	tech specs
Kaiser	MTM Programs	Field II.L: Date of annual CMR, if applicable.	Clarify that response should be provided only for the subset of enrollees who get the CMR.	Clarify	Yes, data element L should be provided only for the subset of enrollees who get a Comprehensive Medical Review.	tech specs

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
Kaiser	MTM Programs	Field II.M: Number of Targeted Medication Reviews. We want to confirm that CMS will give plans the flexibility to determine which elements should be included in the targeted medication reviews. Kaiser Permanente has developed a number of methods to target populations whom we believe will benefit from further interventions from our pharmacists to achieve desired outcomes. For example, Kaiser Permanente identifies members on medications who have labs that are not at goal, and pharmacists can make recommendations to prescribers regarding changes to drug therapy under approved 438954 3/17/2009 3 protocols.	Clarify if we continue to administer these reviews under our own guidelines and protocols and report the number of these reviews.	No Action	This comment is out of the scope of this RR document.	
Kaiser	MTM Programs	Field II.N: Number of Provider Interventions. CMS is requiring that MTM programs offer interventions targeted to providers to resolve medication-related problems. This type of requirement makes sense for Part D sponsors that operate independently of health care delivery systems. However, Kaiser Permanente has an integrated system in which it owns and operates most of its pharmacies and its pharmacists work under collaborative practice agreements with its contracting Permanente physicians. Both the pharmacists and physicians utilize the same electronic medical record, and therefore interventions and recommendations are documented in the health record.	Clarify that this type of collaborative practice would meet this particular requirement and if the number of interventions documented in electronic medical record should be entered into this field.	No Action	This comment is out of the scope of this RR document.	

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
AHIP	MTM Programs	For Section II, elements O-T. Particularly for MA-PD plans that have relationships with network prescribers, MTMPs are used in conjunction with other complementary plan sponsor programs and policies that are designed to serve similar goals. For example, to obtain the number of program interventions (i.e., recommendations) actually implemented through the actions listed in the data elements, it may be necessary to review dispensed drug history, which is likely to require a manual review process. Further, there are significant difficulties in attributing changes in prescriptions directly to MTMP interventions because multiple influences are typically at work. For example, a factor that would call into question a clear linkage between the intervention and any prescription change is the time lag which commonly occurs between the intervention (i.e., recommendation) under the MTMP and the change.	Recommend that if CMS retains data elements O. through T., the agency consider initially implementing these data elements on a voluntary, pilot basis and working with participating plan sponsors to evaluate the methods through which the data may be collected, as well as the extent to which the changes in prescriptions identified in the data elements can be reliably linked to interventions under a MTMP.	Do not accept	Data elements O - T will be revised into one data element (O).	edit
SilverScript Insurance Company/SSLLC	Overpayment	The commenter points out that CMS has deleted the requirement to report overpayments on the basis that it is "unnecessary data collection."	The commenter recommends that CMS delete the requirement to report overpayments for 2009 as well	No Action	This comment is out of the scope of this RR document.	
SilverScript Insurance Company/SSLLC	Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	A comment was received asking if the report format will remain as Tab delimited.	The commenter recommends that CMS should maintain the Tab delimited format.	Clarify	Yes, the report format will remain as tab delimited.	
BCBS of FL	Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	Language	Revise to show change to annual reporting	Accept	Change will be made.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
SilverScript Insurance Company/SSLLC	Pharmacy Support of Electronic Prescribing	Data element A, the number of contracted retail pharmacies, is duplicative of other reporting requirements, specifically, Section 2-A4 and 3B. Duplicate reporting imposes a significant burden on Part D sponsors, since much of the effort is in organizing and reporting the data.	Delete data element A, and use previously reported data from other reporting sections.	Accept	This data element will be deleted, and it will be clearly noted to Plans that the other element will be used to evaluate these data.	edit
AHIP	Pharmacy Support of Electronic Prescribing	Data element C, the total number of all other contracted non-retail types of pharmacies (including home infusion and long-term care pharmacies), and data element D, the number of other non-retail types of pharmacies enabled to receive electronic prescriptions in compliance with Part D standards are unclear.	Clarify if the “non-retail types of pharmacies” includes all pharmacies that are not classified as “retail network pharmacies"; provide examples in addition to home infusion and long-term care pharmacies.	Accept	CMS will revise the collection to specify non-retail as long-term care (LTC) and home infusion (HI) pharmacies. CMS will utilize the counts of LTC and HI pharmacies from the Pharmacy Access reporting section. It will be clearly noted to Plans that these counts will be used to evaluate these data.	edit
SilverScript Insurance Company/SSLLC	Prompt Payment by Part D Sponsors	Most Part D plans have only a negligible number of paper claims from network pharmacies (as opposed to enrollees), and these would occur in exceptional circumstances. These new reporting elements will require a significant investment of time and money to build the appropriate reporting mechanism. Given the very small volume of claims involved (less than one percent and in our experience less that one tenth of one percent of total claims), the commenter does not believe it is a good utilization of plan and program resources to require this reporting. Instead, since the vast majority of pharmacy claims are electronic, the commenter believes CMS should focus on the reporting associated with these claims.	The commenter recommends that CMS exclude reporting on non-electronic pharmacy claims, as long as these only amount to a negligible proportion (e.g. under 1%) of the total number of pharmacy claims processed by the plan.	Do not accept	Both the statute and our regulations include timeframes for prompt payment of non-electronically-submitted claims. For purposes of ensuring compliance with these requirements, it is necessary to collect data on non-electronically submitted claims.	
BCBS of FL	Prompt Payment by Part D Sponsors	Timeframes	Specify if calendar or business days.	Clarify	The timeframes are calendar, not business, days	edit
BCBS of FL	Prompt Payment by Part D Sponsors	Confirm if data element A is sum of B and C.		Clarify	Element A is the sum of elements B and C.	edit
BCBS of FL	Prompt Payment by Part D Sponsors	Confirm if data element D is a subset of B. What is the universe of clean claims?		Clarify	Element D is a subset of element B.	edit
BCBS of FL	Prompt Payment by Part D Sponsors	Confirm if data element E is a subset of C. What is the universe of clean claims?		Clarify	Element E is a subset of element C.	edit

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
HealthPartners	Prompt Payment by Part D Sponsors	The term "non-electronically submitted claims" is not clear.	Clarify the term "non-electronically submitted claims" and provide examples. Are these direct member reimbursement (DMR) requests, provider submitted claims, and/or another claim type?	Clarify	It will be clarified that an example of a non-electronically submitted claim is a paper claim.	edit
Kaiser	Retail, Home Infusion, and Long-Term Care Pharmacy Access	CMS is proposing to remove the statement that MA-PD and cost plans that received a waiver of the retail pharmacy convenient access standards are not required to submit data for subsection A. This change means that plans that have a waiver will no longer be exempt from reporting the percentage of Medicare beneficiaries living within a certain number of miles of retail network pharmacies in urban, suburban or rural areas and that such plans must report the number of contracted retail pharmacies in the Service area.	Recommend CMS retain the reporting exemption for plans with the waiver. The convenient access waiver is based on the number of prescriptions filled at pharmacies owned and operated by the Part D sponsor, so the access information being requested by CMS does not impact the validity of the waiver. One rationale for the waiver is that colocation of pharmacy services with medical care services is inherently convenient and is not reflected in the retail pharmacy access standards. Thus, for plans with this waiver, we do not believe that CMS needs this access information as compiling and providing it puts an unnecessary burden on plans with the waiver and any resulting reports and comparisons will inadequately describe the actual convenient access provided by plan owned and operated pharmacies.	Do not accept	Sponsors receiving waivers will no longer be exempt from reporting retail pharmacy data.	edit
AHIP	Retail, Home Infusion, and Long-Term Care Pharmacy Access	This section contains a typographical error related to the labeling of the data elements, which are identified as “K, L, M, and N.”	Recommend that CMS review and revise the labels as “A, B, C, and D".	Accept	Document will be revised.	edit
SilverScript Insurance Company/SSLLC	Transition	A comment was received that noted the data requested in this Section, while not new, is duplicative of data provided to CMS elsewhere, such as in the bid and plan benefit package. The commenter is concerned with the increasing number of reporting requirements that are not reporting anything new to CMS, but effectively helping CMS organize data it already has from Part D sponsors. If this were relatively easy to do at little cost, the commenter would not object to doing so, but as pointed out previously, the reporting process itself imposes a significant burden, and so the commenter requests that CMS not ask plans to provide information that they have already reported in some form.	The commenter recommends that CMS utilize data already provided by the plan in other documents or reports.	Do not accept	CMS no longer collects or reviews transition policies from sponsors; instead, sponsors are required to attest that they meet the minimum requirements as part of the formulary submission process. Therefore, this data collection does not duplicate information already available to CMS. It is now the only mechanism available to CMS for collecting data on sponsors’ transition processes.	

Reporting Requirements						
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**	**Need to:**
SilverScript Insurance Company/SSLLC	Vaccines	The change from reporting the date the vaccine is processed or adjudicated to the date it is dispensed or administered will result in a significant number of vaccines not being reported. For example, assume a vaccine is dispensed on June 12, but the claim is only submitted on September 1. This vaccine would not be reported in Period 1, since the Part D sponsor will not know of it until after the Period 1 report is due. It will also not be reported in Period 2, since the dispense date falls outside Period 2. Since most plans allow a 90 day window to submit paper claims, this scenario is not at all uncommon. In addition, even if the claim were submitted before the deadline for submission of the report (here August 31), the Part D sponsor will have no ability to pick up these claims that are submitted after the quarter, since its cut off date for data collection will be the end of the quarter (and as a practical matter, it is not possible to continue collecting data until the day or a few days before a report is due). So all claims submitted after the end of the reporting quarter will be lost. The commenter also notes that from the perspective of presenting the most accurate picture of the volume of vaccines covered by the plan in a given period, the process or adjudication date is the more accurate and complete statistic to use, since this is the date the vaccine becomes	It is recommend that CMS continue to use the date of processing or adjudication, rather than the dispense or administered date for vaccine reporting.	Accept	This change is consistent with other reporting sections where data are based on the dispensing or administered date, and not the processing or adjudication dates. Variations in adjudication cycles can create discrepancies in data reported. To address the potential for the time-lag, Period 2 will be revised to a full calendar year, where the Sponsor can update reports to capture examples as listed. reporting periods will be revised MS respectively disagrees with the comment. Elements A - C will continue to be based on when the vaccines were dispensed/immunized. Elements D - F will be based on when the vaccines were processed.	edit

Rep		
Organization	**Page**	**Description of Issue or Question**
DDBP/MDBG		Clarification of Part D Reporting Requirements

orting Requirements	
Suggested Revision/Comment	**CMS ACTION**
Section II, Bundling of Part D Home Infusion Drugs Under a Part C Supplemental Benefit, clarifies the policy on bundling of HI drugs under Part C but does not clarify that Part D reporting requirements must still be met. Request that a sentence is inserted to clarify that MA-PDs choosing to bundle the home infusion drugs under a Part C suppliemental benefit must still meet all Part D reporting requirements related to Home Infusion Pharmacy Access.	Accept.

REASON FOR ACTION
CMS will add clarifying language in Part D RR2010, pending final 2010 Call letter.