Pre-PRA Comments on
CY2013 Part D Reporting Requirements
CMS-10185

Reporting Requirements					
Organization	**Reporting Section**	**Description of Issue or Question**	**Commenter's Recommendations**	**CMS ACTION**	**REASON FOR ACTION**
Silverscript/Pennsylvania Life	Coverage Determinations and Exceptions	**Elements O,P, and Q:** We assume that the following formulas are correct: O is the sum of R, U, X and AA. P is the sum of S, V, Y and BB. Q is the sum of T, W, Z and CC.	Confirm that our assumption is accurate.	Accept	Element O is not the sum of elements R, U, X and AA. Element P is not the sum of elements S, V, Y and BB. Element Q is not the sum of elements T, W, Z and CC. Clarifications will be included in the 2013 technical notes. Elements O, P, and Q include only exceptions to the plan's PA criteria. Elements R, S, and T include only exceptions to the plan's Step Therapy criteria. Elements U, V and W include only exceptions to the plan's quantity limit criteria. Elements X, Y, Z include only exceptions to the plan's tiering structure. Elements AA, BB, and CC include only exceptions to the plan's formulary.
United/AHIP/Express Scripts/Aetna	Grievances	**"CMS Issues data element:** We believe that additional information about the new category would promote a common understanding of the agency's expectation for reporting. Should we refer to Chapter 18, section 20.2 for definition of CMS issues?	Recommend CMS include an explanation of this category that includes examples in the final version of the Reporting Requirements and/or Part D Reporting Requirements Technical Specifications.	Accept	The new grievance category is meant to identify those grievances that are due to CMS issues, and are related to issues outside of the Plan's direct control. This same type of categorization is used in the Complaint Tracking Module (CTM) and allows CMS to exclude those grievances, that are outside of the Plan's direct control, from the total number of grievances filed against the contract. Clarifications will be included in the 2013 technical notes.
Aetna	Grievances	**Introduction language:** For reporting, Plans should: Report data based on the date the grievance decision was made. Track multiple grievances by a single complainant and report as separate grievances…For reporting, Plans should not: Report requests for coverage determinations, exceptions, or redeterminations as grievances...These statements seem contradictory.	Clarify this introductory language.	Accept	Language has been revised in the introduction. For reporting, Sponsors should report For reporting, Sponsors should: • Report data based on the date the grievance decision was made. • Track multiple grievances by a single complainant and report as separate grievances. • Report those grievances that may have also been reported in the Complaints Tracking Module (CTM). Language has been revised in the introduction for Grievances. For reporting, Sponsors should not: • Report requests for coverage determinations, exceptions, or redeterminations inappropriately as grievances. • Report complaints received by 1-800 Medicare or recorded only in the CTM as grievances. • Report general inquiries or questions as grievances. • Dismiss or exclude any grievances filed by beneficiaries or their appointed representatives from this reporting section.
Aetna	MTM	**Element D:** Beneficiary Middle Initial, is normally an optional item. Will the element continue to be optional for 2013 reporting?	Recommend element D, Beneficiary Middle Initial, should be optional.	Accept	Yes, the beneficiary middle initial will be optional for reporting element D. This clarification will be included in the technical notes.

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Organization	**Reporting Section**	**Description of Issue or Question**	**Commenter's Recommendations**	**CMS ACTION**	**REASON FOR ACTION**
United/Aetna/Cigna/Silverscript/ Pennsylvania Life	MTM	**Element I:** Given that medical records are not available for Part D members unless they also have a health plan with the Sponsor, is CMS looking for plans to make arrangements when a member is known to have a cognitive impairment? Will CMS provide guidance on how to determine if a beneficiary is cognitively impaired? Please clarify CMS expectation for identifying cognitive impairment. Does this identification only apply to those beneficiaries in LTC (where claim indicates a LTC setting),or to all beneficiaries? Since medical information is not included on pharmacy claims, does CMS have a recommendation for identifying cognitive impairment, or is clinician, beneficiary or caregiver self-reporting adequate? If the expectation is to report this for all beneficiaries participating in the MTMP and not only those in an LTC setting, then the plans would need to rely on self-reporting to obtain this data, as there would be no other reliable option for access to this information. If CMS is expecting a medical diagnosis of cognitive impairment, is there a specific definition/coding for cognitive impairment that should be utilized?	Recommend CMS confirm that the definition of "cognitive impairment" is intended to be an objective determination made by the plan based on available evidence such as the member having an appointed representative. Recommend CMS provide guidance to Part D Sponsors on how to determine if a beneficiary is cognitively impaired. Recommend that CMS (i) allow plans to accept self reporting of this information to the plan; (ii) allow plans to report 'unknown' for any beneficiary for which information was not obtained, and (iii) defer the other data collection requirements with regard to this data element until such time as an industry standard can be devised to simplify and standardize this reporting.	Do Not Accept	The CMR may be performed with the beneficiary's prescriber, caregiver, or other authorized individual if a beneficiary is offered the annual CMR and is unable to accept the offer to participate (cognitively impaired). In the final rule effective 1/1/2012 (4157-FC), CMS stated that: "…LTC consultant pharmacists are positioned to help plan sponsors work with LTC facility staff to identify cognitively impaired beneficiaries in LTC settings and determine whether beneficiaries are capable of participating in a CMR. CMS recommends that plan sponsors coordinate with LTC consultant pharmacists to make these determinations. If asked, plan sponsors should be able to present documentation or a rationale for these determinations. Any changes to the Part D reporting requirements are outside the scope of this regulation.
Cigna	MTM	**Element J:** Is this the initial date of enrollment in MTM, or the current CY?	Clarify element J.	Accept	Please report current CY MTM enrollment date.
Cigna/Silverscript/Pennsylvania Life	MTM	**Element K:** Please clarify if this is for current CY, and if this is optional if the beneficiary did not meet the requirements. Since targeting reports are generated periodically (e.g., quarterly), beneficiaries may appear on multiple (but not all) targeting runs. Please confirm that the date you are expecting here is the first instance that the targeting criteria were met, as opposed to the most recent instance that the targeting criteria were met.	Clarify element K.	Accept	Please report date for current CY. Reporting should include the first instance of eligibility in CY.
Cigna	MTM	**Element L:** Clarify if optional field that can be left blank.	Clarify element L.	Accept	This element is conditionally required. The date must be entered if the beneficiary opted out of MTM. This will be included in the technical notes.
Cigna	MTM	**Element M:** Clarify is optional field that can be left blank.	Clarify element M.	Accept	This element is conditionally required. The reason must be entered if the beneficiary opted out of MTM. This will be included in the technical notes.
Cigna	MTM	**Element N:** For this metric, is one offer sufficient to answer yes? i.e. can we consider the initial mailed offer for a CMR to answer yes to this metric?	Clarify element N.	Accept	Yes, one offer is sufficient to answer yes to element N. However, the initial mailing date is not sufficient if the offer was not delivered.
AHIP	MTM	**Introduction and elements N, P and V:** We note that several of the proposed data elements appear to be inconsistent with the introductory language. For example, element N would require sponsors to specify for each reported beneficiary whether the beneficiary was offered an annual CMR. Although the introductory language appears to indicate that beneficiaries in all plan sponsor MTM programs must receive CMS-required MTM services, element N appears to require the CMR only for beneficiaries who meet "the specified targeting criteria per CMS Part D requirements." The descriptions for elements P and V raise similar issues.	Recommend CMS review the introductory language and the related data elements and revise this section of the reporting requirements as needed to ensure clarity and consistency.	Do Not Accept	CMS believes that the introductory language is clear and consistent with all data elements. The data elements, where applicable, reference that reporting is based on the specified targeting criteria per CMS - Part D requirements. Element G is included to capture reporting that is not based on the specified criteria per CMS - Part D requirements. We will use all data elements in our analysis of this reporting.
Express Scripts	MTM	**Element Q:** Because the interactive CMR was completed, even if the written summary is returned in the mail, then the beneficiary will still be counted as receiving a CMR.	Confirm this is correct for reporting.	Accept	This is not correct. If a CMR is completed with an MTM member and their CMR Standard Format written summary is returned as non-deliverable, then the plan sponsor should not still count as a CMR. Plan sponsors should confirm contact information at the time of the CMR and should make multiple attempts to reach beneficiaries.
United	MTM	**Element R:** The annual data validation audit should ensure that that dates of the CMRs match up to the reporting year and to the number reported in element Q; therefore, requiring reporting of the CMR dates is not necessary.	Recommend removing element R.	Do Not Accept	CMS developed the data validation audit around the reporting elements. If this is not collected through the reporting requirements, data validation reviewers will not audit these data.
AHIP	MTM	**Element S:** The distinction between the terms "telehealth consultation" and "telephone" is unclear.	Recommend CMS include an explanation in the Part D Reporting Requirements Technical Specifications.	Accept	CMS will include this clarification in the technical notes.

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United	MTM	**Element T:** Is the intent of this data element to assess the level of medical expertise of the person performing the CMR? If that is the case, then categorizing pharmacists by employer may be necessary.	Recommend that CMS limit choices to the broad category of pharmacists, rather than splitting into all of the pharmacist subtypes.	Do Not Accept	CMS would like to collect these data at this level to analyze the types of pharmacists performing CMRs; therefore categories will not be reduced.
AHIP	MTM	**Element T:** Our understanding is that there is the potential for inconsistent understanding by Part D sponsors of the distinctions among some of the listed pharmacist types.	Recommend CMS revise element T to include the single category "pharmacist." If CMS does not adopt this recommendation, we urge CMS to provide greater clarity regarding the various types of pharmacist types.	Do Not Accept	CMS would like to collect these data at this level to analyze the types of pharmacists performing CMRs. CMS believes the categories given are self-explanatory.
United	MTM	**Element U:** CMS requires that plans identify "beneficiary's prescriber, caregiver, or other authorized representative" as a data element but "other authorized representative" is not defined. In the April 10, 2012 CMS memo titled "CY2013 Medication Therapy Management Program Guidance and Submission Instructions." CMS directed plans to identify "other authorized representatives such as the resident's health care proxy or legal guardian."	Clarify definition of "other authorized representative."	Accept	Please use the same definition and/or examples for "other authorized representative" as those provided In the April 10, 2012 CMS memo titled "CY2013 Medication Therapy Management Program Guidance and Submission Instructions." In this memo, plans are directed to identify "other authorized representatives such as the resident's health care proxy or legal guardian."
Cigna	MTM	**Element U:** For this metric, it is clearly marked that the Beneficiary's prescriber is an option as a recipient. Is this possible for any beneficiary's CMR, or only those with cognitive impairment?	Clarify element U.	Accept	This is limited to those beneficiaries that are identified as cognitively impaired.
Cigna	MTM	**Element W:** For this metric, is there a specific audience? Is this considered to be the physician only?	Clarify element W.	Accept	The specific audience is prescribers. Language has been updated in element W to clarify this. Element W now reads 'Number of drug therapy problem recommendations made to prescriber(s) as a result of MTM services.'
AHIP	MTM	**Element W:** It is our understanding that this information is generally documented in the beneficiary's medical chart and therefore, is not available through administrative data. As a result, we continue to be concerned about practical issues faced by Part D Sponsors, particularly sponsors of stand alone Part D plans, in complying with this requirement, including the investment of time and level of staffing required to collect and accurately report these data to CMS.	Recommend CMS evaluate further the feasibility of reporting element W.	Accept	Previously, a prescriber intervention (e.g. a letter) with multiple recommendation would count as 1 intervention. Element W reports the number of distinct recommendations. So if one letter makes 5 distinct recommendations, it would count as 5 recommendations, but if they make the same recommendations to other prescribers, they cannot double count. This is a change from 2012 Part D MTM reporting where plans are required to report interventions instead of recommendations. This will be noted in the 2013 technical notes.
Cigna	MTM	**Element X:** Is there a specific method that must be followed to consider this a changed drug?	Clarify element X.	Accept	Sponsors should retain documentation supporting the number of changes to drug therapy reported to CMS. If the change was observed in the calendar year after the current reporting period by the reporting deadline (e.g., February 28), but was the result of an MTM intervention and drug therapy recommendation made within the current reporting period, the change may be reported for the current reporting period. However, this change to drug therapy cannot be reported again in the following reporting period. This clarification will be included in the 2013 technical notes.
Kaiser Foundation/Express Scripts	MTM	**Element X:** Seeking additional clarification because in its integrated practice model, pharmacists are working under collaborative practice protocols with physicians. As a result, recommendation are not always necessary; the pharmacists make the "drug therapy resolution" in some cases, while for others, recommendations are made. For this element, would the "number of drug therapy problem resolutions made as a result of recommendations" include both the number of drug therapy problem resolutions made with and without recommendations. One opportunity could produce multiple therapy changes. Therefore, element W may count one intervention and element X may count multiple therapy changes as a result of that one intervention.	Clarify element X.	Accept	Previously, a prescriber intervention (e.g. a letter) with multiple recommendation would count as 1 intervention. Element X reports the number of distinct drug therapy changes made as a result of the MTM recommendations (element W). CMS agrees that 1 intervention with one or more recommendations could produce multiple distinct changes. This will be noted in the 2013 technical notes.
AHIP	MTM	**Elements Q and R:** The value of including these requirements as separate elements is unclear.	Recommend CMS consider combining elements Q and R, or if separate elements are retained, that CMS clarify the purposed of collecting both elements.	Do Not Accept	Elements Q and R will not be combined. This information needs to be separated for analysis purposes.

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Health Partners	MTM	**Gentran/TIBCO system:** We would like to see the Reporting Requirements/Technical Specifications provide more detail around the use of the Gentran, soon to be TIBCO, system,	We would like TIBCO to be updated in the Reporting Requirements and Technical Specifications as it is replacing Gentran. We would like more detail regarding the levels of confirmation a plan would receive and the timing of these notices.	Do Not Accept	CMS will not provide details about TIBCO in the Reporting Requirements or technical notes as this is outside the scope of the Reporting Requirements. CMS will provide details about TIBCO in a HPMS memo which is expected to be released in January 2013.
United	Plan Oversight of Agents	**Elements B - I:** These data elements appear to assume that agents are employed/captive or independent. However, agents may be both employed/captive and independent at different points in the same reporting period. Can CMS provide guidance on how plans should report agents who were both employed/captive and independent at different point in the same reporting period?	Clarify how to report agents who were both employed/captive and independent at different points during the same reporting period.	Accept	For agents that were both employed/captive and independent at different points during the same reporting period, report them under the category in which they made the most assisted enrollments during the reporting period. This is the most valid way to report agents that served in both capacities.
Silverscript/Pennsylvania Life	Plan Oversight of Agents	**Element B:** It is not clear what the difference is between an employed and captive agent.	Define the term "captive agent".	Accept	Section 120.4.4 of the Medicare Marketing Guidelines describes captive agents as a contracted agent representing "a single plan sponsor and is paid a fixed amount of money that doesn't vary based on enrollment." This agent may also receive a commission based on volume of sales.
Silverscript/Pennsylvania Life	Plan Oversight of Agents	**Element J:** Please clarify whether element J equals the total of elements H plus I, or whether J equals the total of elements H plus I plus any Non-Assisted enrollments.	Clarify the requirements as to this question.	Accept	J equals the total of elements H plus I plus any Non-Assisted enrollments. This is CMS' attempt to gather data on all enrollments and be able to calculate the percent that were assisted.
Kaiser Foundation	Redeterminations	**Re: language that states, "Part B vs. D redeterminations should be included in this reporting."** Kaiser seeks additional clarification about whether this includes both situations where the original determination was for coverage of the drug under Part B and where the original determination was coverage of the drug under Part D.	Clarify proposed language "Part B vs. Part D redeterminations should be included in this reporting."	Accept	Yes, this includes both situations where the original determination was for coverage of the drug under Part B and where the original determination was for coverage of the drug under Part D. This will be noted in the 2013 technical notes.