Responses to 60-Day Public Comments on CY2012-2014 Part D Reporting Requirements
CMS-10185

Reporting Requirements					
Organization	**Reporting Section**	**Description of Issue or Question**	**Suggested Revision/Comment**	**CMS ACTION**	**REASON FOR ACTION**
Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Coverage Determinations and Exceptions	Can CMS please clarify the rationale for reporting multiple transactions for the same beneficiary, same drug, same pharmacy, same rejection reason on the same date of service? It is recommended for Report element A- The total number of pharmacy transactions in the reporting time period be further refined to specify the types of pharmacy transactions should be included (example specifying only paid claims, rejected claims and reversed claims and eliminating any other types of transactions such as adjustments which are purely done for financial reasons and do not impact drug utilization management).	It is recommended for Report element A- The total number of pharmacy transactions in the reporting time period be further refined to specify the types of pharmacy transactions should be included (example specifying only paid claims, rejected claims and reversed claims and eliminating any other types of transactions such as adjustments which are purely done for financial reasons and do not impact drug utilization management).	Do not accept	For this reporting section, CMS wants to see all types of pharmacy transactions; therefore, no further clarity needed.
Medco Health Solutions, Inc	Coverage Determinations and Exceptions	All the following elements use the word “processed” in the reporting period. Can CMS clarify what they mean by “processed?” Is it CMS’ expectation that cases be reported when they are decided and not when they are requested? Elements: C. Total number of PAs processed in the reporting period, F. Total number of UM exceptions processed in the reporting period, I. Total number of tier exceptions processed in the reporting period, L. Total number of formulary exceptions processed in the reporting period	Can CMS clarify what they mean by “processed?” Is it CMS’ expectation that cases be reported when they are decided and not when they are requested?	Clarify	Yes, it is CMS' expectation that that cases be reported when they are decided; therefore, for better clarity the word "processed" will be changed to the word "made."
UnitedHealth Care	Employer Group Plan Sponsors	The Employer Group Plan reporting requires sponsors to provide the current (or anticipated) enrollment for each employer group plan. Employer group plans with no or low membership may retroactively add or remove membership between the time the report is due to CMS and when CMS audits for overdue reporting. The Plan cannot anticipate or control when this membership retroactivity will occur which may cause a gap between CMS and Plan employer group membership records. When overdue notices were received, it was confirmed that all of the overdue notices received pertained to plans with no membership and/or with no employer groups. In these instances CMS instructed the sponsor to disregard the notices. However, we are concerned about how these notices will be tracked to ensure that CMS' records accurately capture plan compliance with the reporting timeframes. We recommend that when sponsors validate there is no EGHP membership or no employer groups, that CMS officially rescind or withdraw the overdue notices.	We recommend that when sponsors validate there is no EGHP membership or no employer groups, that CMS officially rescind or withdraw the overdue notices.	No action	We understand the recommendation, but this does not really pertain to the “information collection requirements” per the Paperwork Reduction Act. However, we note your comment.
Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Enrollment and Disenrollment	Effective 4/18/2011 CMS is introducing changes to the enrollment processing rules (MARx System Re-design – April Software release). The change result in elimination of certain type codes such as code 60, 62. Therefore section below should be modified accordingly to include proper codes: Data elements 1.A-1.P must include all enrollments (60, 61, 62 and 71 transactions)	Section below should be modified accordingly to include proper codes: Data elements 1.A-1.P must include all enrollments (60, 61, 62 and 71 transactions)	Accept	This section will be revised to include all enrollment transactions.
Independent Health	Enrollment and Disenrollment	These changes are significant. If an existing report from our enrollment vendor cannot accommodate these changes, then this would be a very manual report, and very cumbersome to report on.		No action	We understand that this section requires some additional burden; however, this additional reporting will assist CMS in its efforts to better analyze Medicare Part C and Part D enrollment and disenrollment data.

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AHIP/ United Healthcare	Enrollment and Disenrollment	***Data Element 1.M.*** Data Element M proposes to require sponsors to report, of the total number reported in Element A, "the number of enrollment transactions submitted using the SEP Election Period code "S" related to change in residence." -The introductory language for this section of the reporting requirements indicates that CMS intends to collect data that are not otherwise available to the agency. However, sponsors are currently reporting to CMS through the enrollment process transactions associated with SEPs for changes in residence. -In addition, it appears that the reference to SEP Election Period code "S" is erroneous; it is our understanding that the SEP associated with changes in residence has been assigned its own Election Period code "V." (See Plan Communications User Guide (PCUG) Appendices, page 140.) We recommend that CMS remove this data element from the proposed Part D Reporting Requirements.	We recommend that CMS remove this data element from the proposed Part D Reporting Requirements.	Accept	Data element 1.M will be removed.
AHIP	Enrollment and Disenrollment	**Data Elements 1.Q., 1.R., and 1.S.** With the exception of Elements Q., R., and S., the descriptions of the data elements explicitly specify that they should be reported as a subset of either Element A. or C. It appears that a reference to Element A may be appropriate in Elements Q., R., and S. If this is correct, we recommend that the reference be added.	If this is correct, we recommend that the reference be added.	Do not accept	Data elements 1.Q, 1.R and 1.S will be removed.
AHIP	Enrollment and Disenrollment	***Data Element 2.A***. Data element A proposes to require sponsors to report the total number of disenrollment requests received in the specified time period. (Emphasis added.) Use of the word, "requests," appears to be in error because the instructions for this reporting section indicate that sponsors must report all disenrollments, which we interpret to mean both voluntary and involuntary disenrollments. However, involuntary disenrollments do not typically involve "requests." For clarity, we recommend element A be revised to explicitly state that voluntary and involuntary disenrollment requests be reported.	For clarity, we recommend element A be revised to explicitly state that voluntary and involuntary disenrollment requests be reported.	Clarify	Data element 2.A will be revised.
AHIP	Enrollment and Disenrollment	***Data Element 2.D.*** Data Element D proposes to require sponsors to report, of the total number reported in Element A, the total number of disenrollments that were due to failure to pay premium. The instructions for this reporting section indicate that CMS will collect data on the elements that are "otherwise not available to CMS." However, sponsors are currently reporting to CMS the disenrollment transactions associated with failure to pay premiums. (See PCUG Appendices, page H-106.) We recommend that CMS remove this proposed data element from the Part D Reporting Requirements.	We recommend that CMS remove this proposed data element from the Part D Reporting Requirements.	Accept	Data element 2.D will be removed.
Unknown	Enrollment and Disenrollment	Paragraphs 4 and 5 on page 5. These paragraphs mention transactions that will be going away with the April 2011 software release. Please remove the applicable transactions that will be going away with the April 2011 software release (e.g. 60,62,)	Please remove the applicable transactions that will be going away with the April 2011 software release (e.g. 60,62,)	Accept	CMS will remove the transaction codes which will be going away with the April 2011 software release.
Unknown	Enrollment and Disenrollment	1.B on page 5. It's unclear whether "complete" means complete when received or complete following a request for information. In other words, are 1B and 1C exclusive of each other, or could some of the enrollments in 1C also be in 1B? Please clarify.	Please clarify.	Clarify	Data element 1.B will be revised.
Unknown	Enrollment and Disenrollment	1.J on page 6. It's unclear exactly what is meant by "employed" agents and brokers. It's unclear exactly what is meant by "employed" agents and brokers. Please provide a definition for employed agents/brokers.	Please provide a definition for employed agents/brokers.	Accept	Data element 1.J will be revised to refer to "sales persons" consistent with Medicare Marketing Guidelines.

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Unknown	Enrollment and Disenrollment	2.A on page 6. Should plans include only voluntary disenrollments for this element? Meaning we would exclude out-of-area or incarcerated disenrollments. Please add clarifying language.	Please add clarifying language.	Clarify	Data element 2.A will be revised.
Unknown	Enrollment and Disenrollment	2.B on page 6. It's unclear whether "complete" means complete when received or complete following a request for information. Please clarify.	Please clarify.	Clarify	Data element 2.B will be revised.
Unknown	Enrollment and Disenrollment	2.C on page 6. Should the the number of disenrollment requests denied include both denials for ineligibility and denials for not responding to a request for information? Please add clarifying language.	Please add clarifying language.	Clarify	Data element 2.C will be revised.
Unknown	Enrollment and Disenrollment	2.D on page 6. Disenrollments due to failure to pay premium would not be voluntary and based on the answer to 2.A above would probably not be included in "total reported in A." Please clarify.	Please clarify.	Accept	Data element 2.D will be removed.
UnitedHealth Care	Enrollment and Disenrollment	The Part C and Part D Enrollment and Disenrollment Reporting Requirements Data Element D. notes of the total reported in A, report the number of enrollment requests denied due to determination of the ineligibility to elect the plan (e.g. individual not having a valid enrollment period.). Is CMS requesting the number of enrollments denied by the Plan (40.2.3 - MA Organization Denial of Enrollment) or denied by CMS or both?	Please clarify.	Clarify	Data element 1.D will be revised.
Wisconsin Physicians Service Health Insurance Corp.	Enrollment and Disenrollment	Under Number 1., Letters Q., R., and S., are data that is sent to plans by CMS. Is there a reason that we are required to report back data that CMS already has record of?		Accept	Data elements 1.Q, 1.R and 1.S will be removed.
Wisconsin Physicians Service Health Insurance Corp.	Enrollment and Disenrollment	Under Number 2., letter C., is the amount denials from CMS, by the Plan, or both?	Please clarify.	Clarify	Data element 2.C will be revised.
UnitedHealth Care	General	We request CMS publish a guide to the validation standards that the data files must pass in order to be accepted by HPMS. During the upload for Measures, our organization experienced a few rejections based on the validation standards, but did not have clear sight as to what those standards were. WIthout knowing what the standards are, errors can be difficult to correct, and, once corrected, plans may experience another error based on a different standard during submission of the same file. If organizations understood the validation standards, files could be quality checked and errors avoided during uploading of the files.	We request CMS publish a guide to the validation standards that the data files must pass in order to be accepted by HPMS.	Do not accept	We believe the commenter is confusing the data reporting with the Part C/D Data Validation Standards. The submitted data should be accepted into HPMS if there are no formatting issues. QA procedures such as outlier analysis are performed on the data after they have been accepted into HPMS and, therefore, should not result in rejection during the upload.
UnitedHealth Care	General	We request CMS provide Plans with the Part C and Part D Reporting outlier statements and calculation methodology for each of the required reports. This information could be used to assist Plans in the interpretation of the Part C and Part D Reporting Requirements and Technical Specifications; support reporting decisions; and support Plans internal identification of potential data issues. If CMS will not provide the calculation methodologies, we request, at a minimum, that the outlier statements be provided.	We request CMS provide Plans with the Part C and Part D Reporting outlier statements and calculation methodology for each of the required reports.	Do not accept	CMS will not make outlier information available to the Plans at this time. Currently, we do not have fixed thresholds for all the sections. Plans would not be able to duplicate our process, and, therefore, we do not believe it would be beneficial to supply this information.

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Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Long-Term Care (LTC) Utilization and Waste	For Element D: 1. We are concerned that plans currently do not have a way to track returns on elements 5-8. Plans do not directly contract with LTC facilities, thus will not have the authority to "require" LTC facilities to return unused medications to LTC pharmacies. Additionally, neither plans nor PBMs have a way to receive this type of information from LTC pharmacies or any other type of pharmacy. Specifically, currently there is no data or system that is able to support and capture the "return information" between LTC facilities and pharmacies and then trace a returned medication back to an individual processor (PBM) at the individual plan, beneficiary, and claim level. NCPDP returns standards will not be available until 2014.		No action	Part D sponsors will be required to collect return information through a more manual process until a transaction standard is approved. We believe this reduced burden is warranted by the need to obtain information to assist with quantifying the residual waste.
Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Long-Term Care (LTC) Utilization and Waste	What will CMS do with the "chain code" value (e.g., are the 'rolling up' the data to ownership level to examine the patterns of returns by each owner of the chain? Additionally, which "chain code" value is to be used (NCPDP or Medco's) in the reporting? Is "affiliation code" appropriate/needed for independents as CMS might be looking a network contract (versus ownership) patterns?		Clarify	This section has been revised to include the chain code for LTC utilization reporting. We will not collect the chain code for LTC waste reporting. When reporting, plans should refer to the chain code provided by NCPDP. CMS will be analyzing the LTC utilization patterns/trends for the various types of pharmacies.
Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Long-Term Care (LTC) Utilization and Waste	Do the "cost" values include patient cost share (OOP cost of the ingredient) or only the plan's share?		Accept	We will amend the requirement to only include the total ingredient costs. Total ingredient costs, for the purposes of this reporting requirement, equal the costs paid by the plan and the costs paid by the beneficiary/government.
Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Long-Term Care (LTC) Utilization and Waste	Do LTC facilities include all but ALFs and then reporting on returns would only be for those claims paid as LTC (not retail as with an ALF)?		No action	LTC facilities are defined in § 423.100 and do not include ALFs. The reporting requirements pertain to any Part D sponsor's pharmacy dispensing to enrollees residing in LTCFs.
Universal American	Long-Term Care (LTC) Utilization and Waste	Subsection D.5-D.8 (page 19) are not currently feasible to report as these are not submitted/collected in any way as part of a submitted and/or reversed claim. Additionally, this methodology would still not account for drugs that are not returned, rather destroyed. Suggestion to remove this requirment until such time that NCPDP can include appropriate fields with the claim segment to capture this information.	Suggestion to remove this requirment until such time that NCPDP can include appropriate fields with the claim segment to capture this information.	Do not accept	We will change the requirement to have Part D sponsors report to CMS the dispensing methodology used. Clarification will be provided in the technical specifications –The types of dispensing methodologies are: 7-day, 4-day, 3-day, 2-day, 1-day, 4-3-day, 2-2-3-day, 14-day, automated on demand dosing, and other.
AHIP	Long-Term Care (LTC) Utilization and Waste	***Data Element D.*** Data Element D proposes several new items (specifically items 5-8) related to the reporting of the total number of returned prescription drugs and the total cost of the returned drugs for each network LTC pharmacy in the Part D sponsor's service area. It is our understanding that there is currently no standard transaction for use by LTC pharmacies in reporting to the plan sponsor the drugs that have been returned from a LTC facility back to the pharmacy. We recommend that CMS delay implementation of the proposed new items 5-8 of Element D. under this section of the reporting requirements until a suitable standard has been developed by NCPDP.	We recommend that CMS delay implementation of the proposed new items 5-8 of Element D. under this section of the reporting requirements until a suitable standard has been developed by NCPDP.	Do not accept	We will change the requirement to have Part D sponsors report to CMS the dispensing methodology used. Clarification will be provided in the technical specifications –The types of dispensing methodologies are: 7-day, 4-day, 3-day, 2-day, 1-day, 4-3-day, 2-2-3-day, 14-day, automated on demand dosing, and other.

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Argus	Long-Term Care (LTC) Utilization and Waste	The timeline requirements for the new data elements specific to waste reporting are overly aggressive given the industry has not defined a transaction to report waste. The industry has provided feedback to CMS through the review of CMS-4144-P. The feedback stated that return tracking should not be implemented until 2015 at the earliest.		Do not accept	We will change the requirement to have Part D sponsors report to CMS the dispensing methodology used. Clarification will be provided in the technical specifications –The types of dispensing methodologies are: 7-day, 4-day, 3-day, 2-day, 1-day, 4-3-day, 2-2-3-day, 14-day, automated on demand dosing, and other.
Argus	Long-Term Care (LTC) Utilization and Waste	For each network LTC pharmacy in the service area: 5. The total number of returned brand solid oral units (tablets, capsules, etc) Please clarify where you would expect us to report brand drugs that are exempt from the 7 day dispensing requirement. For example if inhalers are exempt because they are in a package size that cannot be broken, should these still be reported under Brand?		No action	The reporting requirements pertain to all solid oral doses.
Argus	Long-Term Care (LTC) Utilization and Waste	6. The total cost of these returned brand drugs, where total cost should be calculated as gross drug cost (Ingredient cost + Dispensing Fee + Sales Tax). By including dispense fee and sales tax in the returned drug amount, the potential savings would be overstated. Return for destruction is not a refund. No crediting to plan will be done, therefore dispense fees and sales tax will not be credited. It is strictly the return of the drug and therefore the maximum potential savings would be the cost of the drug and a prorated amount of the sales tax at best (assuming it was never dispensed which is the ideal situation). It is unlikely that the dispense fee will be less therefore including the dispense fee in the estimated amount of savings would be overstating the potential dollars saved.		Accept	We will amend the requirement to only include the ingredient costs.
Argus	Long-Term Care (LTC) Utilization and Waste	8. The total cost of these returned generic drugs, where total cost should be calculated as gross drug cost (Ingredient cost + Dispensing Fee + Sales Tax). By including dispense fee and sales tax in the returned drug amount, the potential savings would be overstated. Return for destruction is not a refund. No crediting to plan will be done, therefore dispense fees and sales tax will not be credited. It is strictly the return of the drug and therefore the maximum potential savings would be the cost of the drug and a prorated amount of the sales tax at best (assuming it was never dispensed which is the ideal situation). It is unlikely that the dispense fee will be less therefore including the dispense fee in the estimated amount of savings would be overstating the potential dollars saved.		Accept	We will amend the requirement to only include the ingredient costs.
Argus	Long-Term Care (LTC) Utilization and Waste	9. By each NCPDP submission clarification code. Need to identify which submission clarification codes referenced. If referring to dispensing frequency, please state that you would like these reported by SCC (submission clarification code) that indicates the frequency of dispensing (i.e. 7 day) Need to identify which submission clarification codes referenced. If referring to dispensing frequency, please state that you would like these reported by SCC (submission clarification code) that indicates the frequency of dispensing (i.e. 7 day)		Accept	We will change the requirement to have Part D sponsors report to CMS the dispensing methodology used. Clarification will be provided in the technical specifications –The types of dispensing methodologies are: 7-day, 4-day, 3-day, 2-day, 1-day, 4-3-day, 2-2-3-day, 14-day, automated on demand dosing, and other.

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Independent Health	MTMP	Data element Q. Number of changes to drug therapy made as a result of MTM interventions. Changes include dosage changes, therapeutic or generic substitutions, and discontinuation of therapy. The 2/28 reporting deadline does not allow for the most accurate picture of the data. For example, there can be many recommendations made to providers each month (including December) and it is not uncommon that responses to these recommendations indicate that the prescriber will discuss with the patient at their next visit. It is not uncommon for the next visit to be 3-6 months later, so complete change data would not be available until June of the following year for December recommendations.	Reporting deadline be changed to a later date.	Do not accept	This is not a new element. In addition, the deadline cannot be pushed back much further as it will affect data validation and the ability to perform analyses in a timely manner. CMS will use PDE and other data along with the plan reported data to evaluate the big picture.
Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Pharmacy Support of Electronic Prescribing	Recommend that CMS eliminate the need for plan sponsors to report this information. It would be more efficient if CMS received this information from a central source such as NCPDP since pharmacies that support electronic prescribing would do so for all Plan Sponsors for which the pharmacy is a network participant. This capability is not a Plan Sponsor specific capability. Recommend that CMS eliminate the need for plan sponsors to report this information.	Recommend that CMS eliminate the need for plan sponsors to report this information.	Do not accept	This reporting helps CMS capture the number of pharmacies in a plan's pharmacy network that support the E-prescribing initiave. This is a reporting section that has been in effect for CY10 and remains in effect through CY11; therefore, this reporting section would have been in effect for two contract years. For CY12 this is only a continuation in reporting for this section.
Medco Health Solutions, Inc/ Wisconsin Physician Service Health Insurance Corp.	Redeterminations	Report Element A- Total number of redeterminations made in the reporting period. Please clarify how these should be reported – should it be based on the date of the redetermination decision?	Please clarify how these should be reported –should it be based on the date of the redetermination decision?	Clarify	Language added to introduction to clarify that redeterminations should be reported based on date of the redetermination decision.