

Revisions Crosswalk (Medicare Parts C and D Data Validation Documentation)

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
1	9/17/2012	DV Standards, FDCF	<p>LTC:</p> <p>MSC-4</p> <p>We would like clarification on what "at the contract level" means specifically. "Applicable Measure-Specific Criteria: MSC-4: Organization accurately calculates the number of network LTC pharmacies in the service area, including the following criteria: MSC-4a: Includes the number of contracted LTC pharmacies at the state level by state for PDPs and RPPOs, and at the contract level for MA-PDs. by service area for MA-PDs. [Data Element A]"</p>	<p>CMS thanks you for your comment. Please note that PDPs and RPPOs are established at the state level, and therefore report at that level (by state). However, MA-PDs are required to report by their entire service area, as their contracts are not established at the state level.</p>	N/A
2	9/17/2012	DV Standards, FDCF	<p>ORGANIZATION DETERMINATIONS / RECONSIDERATIONS:</p> <p>MSC-4</p> <p>In the ODR report (Organization Determinations), Section 2.5, MSC-4 it states "Excludes withdrawals" – removing the word "dismissals". Are dismissals included? This does not match the 2012 Part C Technical Specifications (Version January 2012). In the technical specifications, page 27 under Reporting Exclusions it says to NOT report Dismissals or withdrawals.</p>	<p>CMS thanks you for your comment. This clarification exists in the updated version of the Part C Technical Specifications, expected to be released by October 2012.</p>	N/A

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3	9/17/2012	N/A	The Data Validation documentation is very thorough and is a very useful tool. We encourage you to incorporate the data validation documentation with the current reporting requirements documentation to provide consistent and comprehensive documentation for all reporting requirements. It has been identified that the data validation documents have more detail and provide better guidance on what data should be included/excluded from reporting than the actual reporting requirements documentation available in the technical specs. This has caused inconsistencies when reporting data and then when it is being reviewed by the independent auditors as they are utilizing the data validation documentation.	CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.	N/A
4	9/17/2012	N/A	The Data Validation documentation needs to be finalized and provided to the plans before the 2013 calendar year begins so that this documentation is available as we build are reporting specifications. It is very challenging going into a reporting year when the documentation is finalized several months in the reporting year. This creates inconsistencies in reporting and required possible resubmissions and rework to be performed.	CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.	N/A
5	9/17/2012	N/A	We agree and applaud the proposal to remove the noted data elements from validation. We encourage you to continue to review the elements still requiring validation to ensure it is a value add to have that data validated compared to the costs to administer and validation the information.	CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.	N/A

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6	9/20/2012	N/A	<p>CVS Caremark suggests that the DVR program be validated at the PBM level. This would be significantly more cost effective.</p> <p>We also recommend that CMS shift the audit dates to May through June in order to reduce the burden on the Data Providers for each report measure, as the audits currently coincide with the 1st quarter reporting cycle. Facilitating the Data Validation Review audits along with quarterly reporting activities impacts efficiencies, creates a burden on resources; technical and otherwise.</p>	<p>CMS does not contract with PBMs and therefore does not have the authority to require them to participate in the DV cycle. However, CMS will consider this for future years.</p>	N/A
7	9/20/2012	<p>Technical Specifications, DV Standards, FDCF</p>	<p>We propose consistency between the various documentations (Technical Specifications/Standards/FDCF) which will allow for less misunderstandings of true requirements. Examples include:</p> <p>COVERAGE DETERMINATIONS & EXCEPTIONS:</p> <p>Within the Technical Specification there is no mention within Element A or Notes to include in-network and out-of-network transactions. However, in the Standards/FDCF this requirement is spelled out. Another example is within the same reporting measurement on Elements C-N which excludes members who have UM requirements waived based on an exception decision made in a previous plan year or reporting period. But the Technical Specification utilize the terminology "report on the transaction during the reporting period".</p>	<p>CMS thanks you for your comment. With regards to the inquiries noted in the comment:</p> <ol style="list-style-type: none"> 1. The language "in-network and out-of-network transactions" is outdated and has been removed from the measure-specific criteria. 2. The clarification around waiving UM requirements based on an exception decision made in a previous plan year or reporting period exists in the updated version of the Part D Technical Specifications, expected to be released by October 2012. 	N/A

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8	9/20/2012	Technical Specifications, DV Standards, FDCF	<p>We propose consistency between the various documentations (Technical Specifications/Standards/FDCF) which will allow for less misunderstandings of true requirements. Examples include:</p> <p>REDETERMINATIONS:</p> <p>The 2012 Report Requirements and the Report Technical Specifications Element A and Notes do not include any verbiage that states to include all redetermination requests regardless of who filed the request (e.g., member, appointed representative, or prescribing physician. However, this is being listed as required within the DVR Standards, page 47 under item 5.f.</p>	<p>The language "Includes all redeterminations regardless of who filed the request (e.g., member, appointed representative, or prescribing physician)" is outdated and has been removed from the measure-specific criteria.</p>	N/A
9	9/20/2012	Technical Specifications, DV Standards, FDCF	<p>We propose consistency between the various documentations (Technical Specifications/Standards/FDCF) which will allow for less misunderstandings of true requirements. Examples include:</p> <p>LTC:</p> <p>The Standards make no mention of exclusion of Employer-Direct PDP, Employer-Direct PFFS on the Standards or FDCF. This is mentioned within the Technical Specifications.</p>	<p>The statement in Appendix B and the FDCF ("For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.") has been re-phrased to state:</p> <p>"Employer-Direct PDPs, Employer-Direct PFFS, and any other contracts that have only 800 series plans are excluded from this reporting. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded."</p>	N/A

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10	9/20/2012	Technical Specifications, DV Standards, FDCF	CVS Caremark received confirmation from CMS on August 23, 2012, to exclude all 800 plan data from the 2011 and 2012 LTCU reports. We recommend that all documentation - Technical Specifications, Data Validation Standards and FDCF reflect this new guidance.	The statement in Appendix B and the FDCF ("For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.") has been re-phrased to state: "Employer-Direct PDPs, Employer-Direct PFFS, and any other contracts that have only 800 series plans are excluded from this reporting. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded."	N/A
11	9/20/2012	FDCF	COVERAGE DETERMINATIONS AND EXCEPTIONS: MSC-3 We recommend that the dates reflect the appropriate quarterly reporting due dates, which are 05/31, 8/31, 11/30 and 02/28.	The dates in the FDCF have been updated to correctly reflect the reporting due dates of: 05/31, 8/31, 11/30 and 02/28.	N/A

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12	9/20/2012	DV Standards, FDCF	<p>COVERAGE DETERMINATIONS AND EXCEPTIONS:</p> <p>MSC-7</p> <p>Based upon the Technical Specification documents this measurement should be based upon "decision date". However, the Standards and FDCF mention "date of receipt". We recommend that the Standards and FDCF be updated with the current reporting requirements and technical specifications. Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for fewer misunderstandings of true requirements.</p>	<p>The Data Validation standards have been updated to correspond with the Part D Technical Specifications to correctly state "date of decision."</p>	N/A

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13	9/20/2012	DV Standards, FDCF	<p>LTC:</p> <p>MSC-4 (FDCF only) MSC-7 MSC-8 MSC-9</p> <p>We propose that for Elements Da-Dh), subsections 4d, 7d, 8e and 9f (Elements Da-Dh) – “including those without a physical location/address in the service area”, this language be removed. This language was not present within the last edition of the Reporting Technical Specifications. It was only stated as “Any Long-Term Care pharmacy holding a license for the state(s) in the sponsor’s service area should be included”. We recommend that the Standards and FDCF be updated with the current reporting requirements and technical specifications. Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for fewer misunderstandings of true requirements.</p>	This is additional clarification that does not result in contradictory information between the Technical Specifications and the Data Validation Standards.	N/A

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14	9/20/2012	DV Standards, FDCF	<p>LTC:</p> <p>MSC-10 MSC-11</p> <p>We are suggesting clarification between the Standards and FDCF and the Technical Specification on Elements Ea-Ed, subsection 10a. Conflicting information between the Standards/FDCF that PDP's, RPPO's and MA-PD's be report at the contract level. However, in the Technical Specification it states service area and contract level? We recommend that the Standards and FDCF be updated with the current reporting requirements and technical specifications. Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for fewer misunderstandings of true requirements.</p>	<p>Measure-specific criteria 10 and 11 have been updated to correctly reflect that MA-PDs report at the contract level while PDPs and RPPOs report at the state level.</p>	N/A
15	9/20/2012	DV Standards, FDCF	<p>PLAN OVERSIGHT OF AGENTS:</p> <p>MSC-4</p> <p>We suggest that the 4a substandard be removed from the Standards and FDCF since this requirement is not in the latest Technical Specification. We recommend that the Standards and FDCF be updated with the current reporting requirements and technical specifications. Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for fewer misunderstandings of true requirements.</p>	<p>The following statement exists in both the Part C and Part D Technical Specifications and aligns with MSC-4:</p> <p>"The "number of agents" includes only agents who were licensed to sell on behalf of the Parent Organization, either by being a direct employee or by contractual arrangement, regardless of whether the agent is actively selling during the reporting period."</p>	N/A

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16	9/20/2012	DV Standards, FDCF	<p>PLAN OVERSIGHT OF AGENTS:</p> <p>MSC-9</p> <p>We suggest that the 9e substandard be removed from the Standards and FDCF since this requirement is not in the latest Technical Specification. We recommend that the Standards and FDCF be updated with the current reporting requirements and technical specifications. Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for fewer misunderstandings of true requirements.</p>	<p>Measure-specific criteria 4c and 9e have been removed from the Data Validation Standards to remove ambiguity. Data related to terminated agents should not be excluded from the counts submitted to CMS for the Plan Oversight of Agents measure.</p>	N/A
17	9/20/2012	DV Standards, FDCF	<p>PLAN OVERSIGHT OF AGENTS:</p> <p>MSC-9</p> <p>We suggest that the 9f substandard be removed from the Standards and FDCF since this requirement is not in the latest Technical Specification. We recommend that the Standards and FDCF be updated with the current reporting requirements and technical specifications. Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for fewer misunderstandings of true requirements.</p>	<p>CMS thanks you for your comment. The following clarification exists in the updated version of the Part C Technical Specifications, expected to be released by October 2012:</p> <p>"If a member switches enrollment from one benefit package to another, within the same contract, and uses the services of a licensed agent, this does not count as an agent-assisted enrollment for reporting of element 12.6."</p>	N/A

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18	9/20/2012	DV Standards	<p>MTM: MSC-5d</p> <p>It is recommended that the exact wording that CMS uses in the 2012 Technical Specifications be used: "A targeted beneficiary should only be reported once per contract year per contract file". Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for fewer misunderstandings of true requirements.</p>	<p>CMS thanks you for your comment. MSC-5d has been updated as follows to reflect the updated language in the Part D Technical Specifications: "Includes and reports each targeted member, reported once per contract year per contract file, based on the member's most current HICN."</p> <p>Also, please note that the measure-specific criteria have been standardized to use the term "member."</p>	N/A
19	9/20/2012	DV Standards, FDCF	<p>MTM: MSC-5b</p> <p>Please revise the verbiage of this requirement to clarify that this requirement includes only the Vaccine Administration Fee and does not include any other administration fees. Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for less misunderstandings of true requirements.</p>	<p>The measure-specific criteria have been updated to clarify that the "vaccine administration fee" is the only administrative fee included in the calculation. We will update the Technical Specifications at a later date to coincide.</p>	N/A

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20	9/20/2012	DV Standards, FDCF	<p>MTM:</p> <p>MSC-9</p> <p>Since the Beneficiary Eligible File has the ability to provide up to 3 dates in reference to when a CMR occurred (Element N), we suggest that this same terminology be included within the Standards and FDCF.</p> <p>Consistency between the various documentations (Technical Specifications/Standards/FDCF) will allow for less misunderstandings of true requirements.</p>	<p>MSC-9a has been updated to read as follows:</p> <p>"Properly identifies and includes the date(s) (up to three) the member received a CMR, if applicable. The date occurs within the reporting period, is completed for every member with a "Y" entered for Field Name "Received annual comprehensive medication review," and if more than one comprehensive medication review occurred, includes the date of the first CMR."</p>	N/A
21	9/20/2012	DV Standards	<p>COVERAGE DETERMINATIONS AND EXCEPTIONS:</p> <p>MSC-7a</p> <p>Please revise the verbiage of the requirement to clarify that this data element is based upon the date of decision, not on the date of receipt.</p>	MSC-7a has been updated to correctly state "date of decision."	N/A
22	9/21/2012	DV Standards, FDCF	<p>GRIEVANCES - PART C:</p> <p>Part C Grievance measure needs to have a note about excluding withdrawn grievances similar to that of Part D Grievance measure</p>	The Part C Technical Specifications and measure-specific criteria will be updated to exclude withdrawn Part C grievances for the 2013 reporting year.	N/A
23	9/21/2012	DV Standards, FDCF	<p>REDETERMINATIONS:</p> <p>Part D Redeterminations needs to clarify whether to include or exclude Part B verse Part D coverage appeal decisions</p>	This will be updated in the Part D Technical Specifications and MSC for the 2013 reporting year.	N/A

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24	9/21/2012	DV Standards, FDCF	LTC: MSC 6 & 7 Needs a note about Location code restriction for Element D, similar to that described in Element C	The Part D Technical Specifications has been updated to state that "Claims with patient residence code 03 may be used to identify enrollees. The LTI report may be another tool for this reporting." Also, the note in Allowable Values re: location code 04 and 07 has been removed. In addition, MSC-6d has been updated to align with the changes to the Part D Technical Specifications.	N/A
25	9/21/2012	DV Standards, FDCF	LTC: Needs a note whether as to Element A has to match with the record counts of Element D	The Part D Technical Specifications have been updated to specify that Data Element E is a subset of Data Element B. In addition, MSC-10f and 11g have been updated to align with this change to the Part D Technical Specifications.	N/A
26	9/21/2012	DV Standards, FDCF	LTC: Needs a note whether as to Element B has to match with the record counts of Element E	The Part D Technical Specifications have been updated to specify that Data Element E is a subset of Data Element B. In addition, MSC-10f and 11g have been updated to align with this change to the Part D Technical Specifications.	N/A
27	9/21/2012	DV Standards, FDCF	ORGANIZATION DETERMINATIONS & RECONSIDERATIONS: Needs a note about excluding IRE decisions for all elements i.e., to include only 1st level Plan decisions for all elements	This Part C Technical Specifications and MSC for the 2013 reporting year will be updated to specify that IRE decisions should not be included in the data reported to CMS for this measure.	N/A

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28	9/21/2012	DV Standards, FDCF	ORGANIZATION DETERMINATIONS & RECONSIDERATIONS: Needs a note clarifying whether pre-service means to include pre-authorizations, concurrent authorizations and post-authorizations	Service authorizations include all service-related determinations (as opposed to claims-related decisions) including pre-authorizations, concurrent authorizations, and post-authorizations. The 2013 Technical Specifications will be updated to include this information.	N/A
29	9/21/2012	OAI	Under 3.3 - Table 4 - "Are all required data elements captured by your data system(s)" – Is the emphasis on informing if all elements are captured? Or is the emphasis on whether they were captured internally by the plan's data systems or externally by any others such as a PBM or downstream delegate?	This statement has been re-phrased in the OAI as follows: "Are all required data elements captured by your internal data systems?" Also, an addition column has been added: "If the answer to Column C. is no, please indicate which delegated entities' data systems contain data elements."	N/A
30	9/21/2012	Supporting Statement	Provides preferred method of cost estimation - table 2 or table 3 with few examples. Examples may include scenarios such as organizations having multiple contracts but their underlying data systems are processes are on different platforms mainly due to mergers/acquisitions. Do we consider the base cost plus additional cost per contract as per table 2, or consider table 3 all together, or table 2 or 3 for each merger organization which are on different platforms.	Table 2 assumes that the level of effort is identical for each additional contract, regardless of the underlying technical platform. Table 3 uses this same assumption but is calculated using the average number of contracts per sponsoring organization.	N/A

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31	9/21/2012	DV Standards, FDCF	<p>COVERAGE DETERMINATIONS AND EXCEPTIONS:</p> <p>MSC-7</p> <p>Regarding Appendix 1: Data Validation Standards, please maintain consistency with the Part C and Part D Technical Specifications. Example: Coverage Determinations and Exceptions – Measure Specific Criteria 7 which states to count by date of receipt regardless of when the final decision was made is not consistent with the January 2012 Part D Technical Specifications page 40-41 which states to count based on the date the decision was made.</p>	MSC-7a has been updated to correctly state "date of decision."	N/A
32	9/24/2012	N/A	<p>Types of Information collected – Unfortunately, many of the Part C and D reports requested require that our FIDESNP plan pull and report on data that only partially tells the story of an integrated Medicare and Medicaid plan. Many of the reports ask plans to submit Medicare information only. The actual process of pulling data to report on these requests is often inefficient and requires systems to be reconfigured to pull the data. As a FIDESNP, we look at our performance as an integrated plan not a Medicare Advantage only plan. The added burden of validating this information at years' end requires plans to clearly document and recreate a process that does not tell the full story of the FIDESNP. The type of information collected could be helpful if we were allowed to report both Medicare and Medicaid data.</p>	CMS thanks you for your comment. This information is beyond the scope of the current information collection request. Please submit your comment in response to the Part C Reporting Requirements PRA (OMB Control # 0938-1054, ICF Reference # 201105-0938-008).	N/A

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33	9/24/2012	N/A	Commonwealth Care Alliance (#H2225) feels strongly that the necessity and utility of collecting the defined Parts C and D reporting information does not adequately reflect the Plan's performance of its functions. The process of data collection requires our data analytic team to pull reports – utilizing approximately 30 hours of 1 FTE staff person in order for Commonwealth Care Alliance to meet the regulatory requirements. These reports are not used internally to gage performance standards for Commonwealth Care Alliance since in most reports we only report on Medicare.	CMS thanks you for your comment. Please submit your comment in response to the Part C Reporting Requirements PRA (OMB Control # 0938-1054, ICF Reference # 201105-0938-008).	N/A
34	9/24/2012	N/A	Commonwealth Care Alliance (#H2225) has created additional functional workgroups to support these reports and we estimate that 30-40 hours of work for 1 FTE per submission is required to validate the process and the integrity of data. If these reports were useful to the organization regarding performance and functions, the additional time spent on validating reports would not be bothersome. Unfortunately, the Plan does not use these reports in any operational way other than to meet regulatory requirements.	CMS thanks you for your comment. Please submit your comment in response to the Part C Reporting Requirements PRA (OMB Control # 0938-1054, ICF Reference # 201105-0938-008).	N/A

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35	9/24/2012	DV Standards, FDCF	<p>COVERAGE DETERMINATIONS AND EXCEPTIONS:</p> <p>MSC-12a</p> <p>Coverage Determination Standards, needs to be updated to reflect the Chapter 18 requirements. Please change “after receipt of the request” to after receipt of prescriber supporting statement.</p> <p>Chapter 18, section 30.1 - Prior Authorization or Other Utilization Management Requirements – page 31: the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the physician’s or other prescriber.</p>	<p>MSC-12a has been updated to reflect the requirements stated in Chapter 18 to include only exception decisions for which the member (and the prescribing physician or other prescriber involved, as appropriate) is notified of the decision according to the following timelines:</p> <p>For standard exceptions, the plan must notify the enrollee’s health condition requires, but no later than 72 hours after receipt of the physician’s or other prescriber’s supporting statement.</p> <p>For expedited exceptions, the plan must notify the enrollee’s health condition requires, but no later than 24 hours after receipt of the physician’s or other prescriber’s supporting statement.</p>	N/A

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36	9/24/2012	DV Standards, FDCF	<p>COVERAGE DETERMINATIONS AND EXCEPTIONS:</p> <p>MSC-12b</p> <p>Coverage Determination Standards, needs to be updated to reflect the Chapter 18 requirements. Please change “after receipt of the request” to after receipt of prescriber supporting statement (verbal or written statement).</p> <p>Chapter 18, section 30.1 - Prior Authorization or Other Utilization Management Requirements – page 31: the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the physician’s or other prescriber.</p>	<p>MSC-12b has been updated to reflect the requirements stated in Chapter 18 to exclude favorable exception decision in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:</p> <p>For directly extemporaneous health condition requires, but no later than 72 hours after receipt of the physician’s or other prescriber’s supporting statement.</p> <p>For indirectly extemporaneous health condition requires, but no later than 24 hours after receipt of the physician’s or other prescriber’s supporting statement.</p>	N/A
37	9/24/2012	Technical Specifications, DV Standards	<p>We request that there be one source of truth for the data to be reported and validated. There are a number of edits in the data validation standards that are not addressed in the Part D Technical Specifications or the Part D Reporting Requirements and Technical Specifications. To truly validate the data reported, the audit tool should reflect the instructions for reporting the data.</p>	<p>CMS thanks you for your comment. Please note that the Part C and Part D Technical specifications have been updated to align with the measure-specific criteria.</p>	N/A

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38	9/24/2012	DESI	<p>GRIEVANCES</p> <p>ORGANIZATIONS DETERMINATIONS & RECONSIDERATIONS</p> <p>COVERAGE DETERMINATIONS & EXCEPTIONS</p> <p>REDETERMINATIONS</p> <p>Please clarify what is expected as Source Data, described in Appendix 3, for Grievances, Organization Determinations/Reconsiderations, Coverage Determinations/Exceptions and Redeterminations. The customer service call logs are very extensive and include thousands of calls in a year. A sample of all calls may not demonstrate the data underlying the census/samples records for these measures. Call logs and member letters related directly to the cases in these specific measures would be more appropriate. We would not be able to identify from all customer service call logs, the calls that lead directly to a grievance, for example.</p>	<p>Thank you for comment. As noted in the instructions the source data should represent a random sub-sample of the data underlying the census/sample records. Our intent by this statement is that the source should be related directly to the cases for the specific measures.</p>	N/A
39	9/24/2012	Technical Specifications, DV Standards	<p>GRIEVANCES:</p> <p>Please define what is expected to report and validation for measure 2.4 Grievances for the appeals category. The Technical Specifications do not define what is to be included in this category. Is this to mean a grievance regarding the appeals process? We want to ensure we are not double counting and reporting the same issue more than once.</p>	<p>Yes, an appeals grievance is a grievance regarding the appeals process.</p>	N/A

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40	9/24/2012	N/A	<p>We also suggest that the data validation audit period be adjusted to run from June –August. This would allow for staff preparing the annual bid and PBPs to be available for the data validation audit. We have conflicting deadlines for the staff that work on the bids and are some of the same staff who prepare reports. Moving this audit to after the bid submission deadline would ensure that both projects are completed with full attention and dedication of our staff.</p>	<p>CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.</p>	N/A
41	9/24/2012	Technical Specifications, DV Standards	<p>ORGANIZATIONS DETERMINATIONS & RECONSIDERATIONS:</p> <p>MSC-4b MSC-9a</p> <p>For Appendix 1, measure 2.5 Organization Determinations/Reconsiderations, measure-specific criteria item 4.b. says “prior authorization requests if applicable, regardless of when the request was received.” The Part C Technical Specifications document describes this as completed organization determinations and reconsiderations (i.e., plans have notified enrollee of its decision...). We suggest that the language in Appendix 1 be reworded to read “prior authorization decisions, regardless of when the request was received.” This language is also in item 9.a.</p>	<p>MSC-4b has been updated to remove the language: "...prior authorization requests if applicable, regardless of when the request was received" as this is covered by MSC-4a. In addition, MSC-9a currently reads: "Includes all completed reconsiderations (Part C only) with a date of member notification of the final decision that occurs during the reporting period, regardless of when the request for reconsideration was received."</p>	N/A

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42	9/24/2012	DV Standards	<p>ORGANIZATIONS DETERMINATIONS & RECONSIDERATIONS</p> <p>MSC-4h</p> <p>For Appendix 1, measure 2.5 Organization Determinations/Reconsiderations, measure specific criteria item 4.h. says “include supplemental benefits provided as part of a plan’s Medicare benefit package.” Please clarify what is considered supplemental benefits for this report, would we include Medicare mandatory supplemental benefits only or would we also include optional supplemental benefits? If necessary, we would like to remove optional supplemental benefits.</p>	<p>Appendix 4 of the Part C Technical Specifications contains the following Q&A (#18):</p> <p>Q: "Should supplemental benefit data be excluded from the Part C Reporting?"</p> <p>A: "If the plan’s question refers to value-added items or services (such as extra vision or eye care or a health club membership), such coverage decisions are not appealable under the Subpart M reconsideration process because they are not part of the plan’s benefit package; thus, value-added supplemental data is not reportable under this effort. . However, if a plan includes a supplemental benefit (e.g., a non-Medicare covered item/service) as part of its Medicare benefit package, then a dispute concerning this issue is addressed under the plan’s reconsideration process and the organization determination and reconsideration concerning the supplemental benefit are reportable under this effort."</p>	N/A

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43	9/24/2012	Technical Specifications, DV Standards	<p>PLAN OVERSIGHT OF AGENTS - PART C:</p> <p>MSC-4c MSC-9e MSC-9f</p> <p>We suggest that the Part C Technical Specifications be updated to reflect the changes in the Data Validation Manual and Appendices. For example, the exclusion in measure 2.7 Plan Oversight of Agents, item 4.c and 9.e and f are not addressed in the Technical Specifications. This will cause a difference in the data provided and reviewed for the data validation audit.</p>	<p>Measure-specific criteria 4c and 9e have been removed from the Data Validation Standards to remove ambiguity. Data related to terminated agents should not be excluded from the counts submitted to CMS for the Plan Oversight of Agents measure.</p> <p>In addition, the following clarification exists in the updated version of the Part C Technical Specifications, expected to be released by October 2012:</p> <p>"If a member switches enrollment from one benefit package to another, within the same contract, and uses the services of a licensed agent, this does not count as an agent-assisted enrollment for reporting of element 12.6."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
44	9/24/2012	Technical Specifications, DV Standards	<p>MTM: MSC-4f</p> <p>We request that the Part D Technical Specifications be updated to reflect the exclusion in measure 3.2 MTM, item 4.f to exclude member who received MTM services outside of the CMS required criteria. We take this to mean that if we offer MTM services to members who do not meet the CMS specified criteria, but we feel would benefit from the services, that we do not report these members. However, the Technical Specifications do not make this exclusion and the reported data will not match what is reviewed for the data validation audit.</p>	<p>The updated version of the Part D Technical Specifications for MTM states: "Members who receive MTM services outside of the CMS-required MTM criteria defined by the plan should be excluded from this reporting."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
45	9/24/2012	DV Standards	<p>PLAN OVERSIGHT OF AGENTS - PART C: MSC-4c</p> <p>The proposed data validation standards, specifically for data Element 12.1, indicate that the report should exclude agents who were terminated during the applicable reporting period. Is it the intent of this element to exclude both voluntary and involuntarily termed agents during the reporting period? The reporting period is the entire calendar year by member effective date. Historically, the report included the entire possible selling period for these effective dates and this includes the AEP period of the prior calendar year. The vast majority of our applications are sold during AEP. Many agents sell only during AEP and are then termed in our system. Therefore, any agent who produces during AEP and then terms would be excluded from data elements 12.1 through 12.6 . This may result in zero count across all contracts if termed agents are excluded from the report.</p>	<p>Measure-specific criteria 4c and 9e have been removed from the Data Validation Standards to remove ambiguity. Data related to terminated agents should not be excluded from the counts submitted to CMS for the Plan Oversight of Agents measure.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
46	9/24/2012	DV Standards	<p>SNP:</p> <p>MSC-4a</p> <p>The proposed data validation standards, specifically for the data Element 13.1, indicates that the report should include all members who were eligible for an initial assessment during the current reporting period. Is it CMS' intent for MAOs to report the count of new and existing enrollees who have not completed an initial assessment in 13.1? Also, does CMS intend Plans to report members only once under their most recent plan should they have multiple plan changes during the reporting period?</p>	<p>CMS's answers to the questions submitted are as follows:</p> <p>1. Is it CMS' intent for MAOs to report the count of new and existing enrollees who have not completed an initial assessment in 13.1?</p> <p>Yes</p> <p>2. Does CMS intend Plans to report members only once under their most recent plan should they have multiple plan changes during the reporting period?</p> <p>Yes</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
47	9/24/2012	DV Standards	<p>SNP: MSC-6a</p> <p>For Data Element 13.3, the proposed data validation standards indicate that the report should include all initial assessments that “were completed (within 90 days of enrollment)”. The proposed changes for 13.3 does not account for existing enrollees who had completed an initial assessment in the reporting period. Can CMS provide further guidance how MAOs should apply the 90 day rule to existing members who have not completed an initial assessment? The enrollment date does not appear to be applicable as these members are offered an assessment at the beginning of each plan year.</p> <p>Additionally, for these two SNP Care Management report changes, would CMS consider requesting MAOs to apply these changes beginning with the CY 2012 data submission rather than applying the changes retrospectively with previously submitted data?</p>	<p>CMS will be providing further guidance in the updated version of the 2012 Technical Specifications, expected to be released in October 2012. Please note that while this is a 2011 measure being validated during the 2013 data validation cycle, the 2012 updated Part C Technical Specifications will not contradict the data validation standards applicable to the 2013 data validation cycle. The updated Part C Technical Specifications will provide additional clarification that applies to both the CY 2011 and CY 2012 reporting periods.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
48	9/24/2012	N/A	<p>The schedule that CMS has laid out for the data validation audit does not anticipate an organization which serves members across the country, thus requiring staffing and systems in multiple locations across the country. Completing the rigorous evaluation process that CMS has detailed may require more time than the three months allotted due to the breadth of systems that are reviewed (claims, UM, broker distribution, grievances, appeals, network, exceptions. etc.). We recommend that emphasis should be placed on the meticulous completion of each audit step rather than placing focus on the time taken to complete these steps. In other words, if an organization must start earlier than April 1st to complete the annual data validation audit in full this should be allowed as long as the independent auditor is in agreement that the timing is designed to meet the audit results submission deadline of June 30th.</p>	<p>CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
49	9/24/2012	N/A	<p>We recommend that CMS take additional action to ensure the accuracy and comparability of the Part C and Part D Reported Data. The technical specifications are frequently updated on an ad hoc basis. CMS has also set up Part C and Part D reporting e-mail boxes for Plans to submit questions. However, the answers given via e-mail often do not make it in to the next version of the technical specifications. Sometimes two entities might receive conflicting answers to similar questions. As a result, Plans and even Auditors may have a different interpretation of the requirements than what CMS intended. We recommend that CMS publish an ongoing list of questions / answers on the CMS web site so that both Plans and data validation auditors have line of sight to this additional guidance. Additionally we recommend that CMS set up one or more meetings with Plans and auditors to provide definitive answers to any outstanding questions on the requirements and on the audit itself. The questions and answers could then be added to the running Q/A log noted above.</p>	<p>CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.</p>	N/A
50	9/24/2012	Technical Specifications, DV Standards	<p>We understand that CMS would want auditors to use the same standards for evaluating Plans' compliance with Part C and Part D reporting requirements. However, Plans develop their systems outputs and their business and validation processes based on the published reporting requirements. It is inefficient to undergo validation of requirements that are ambiguous or perhaps erroneous. We recommend that CMS publish a dual document that serves as both the reporting requirements and as the data validation standards.</p>	<p>CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
51	9/24/2012	N/A	<p>We are concerned that this proposal to change the deadline for these reports is highly inconsistent with the goal of the data validation audit of ensuring that Plans are reporting “data that are reliable, valid, complete, comparable, and timely.”</p> <p>Changing the CMS due dates of these reports to 2/28 will require that Plans complete the data extraction, consolidation and validation processes in mid-January. This timeline is in direct conflict with relevant business process timeframes. As a result, these reports will have to be run before Plans have completed all prior year claims processing, before all prior year data is transferred to relevant data warehouses, and before all SNP members’ health risk assessments are completed and collected.</p> <p>Below are the data completeness / accuracy concerns specific to each of the reports:</p> <p><u>SNP Care Management</u></p> <p>The initial health risk assessment for SNP members is required to be completed within 90 days of enrollment. Therefore, members with an 11/1 effective will have up to the end of January to complete the HRA and members with a 12/1 effective will have up the end of February to complete the HRA. When SNP members cannot be reached by phone (a frequent occurrence with dual eligible plan members), our vendor sends the HRA out via mail. That document then needs to be returned by mail, the information processed by the vendor, and the results sent to the Plan. A full HRA dataset would not be available until late March.</p> <p><u>Serious Reportable Adverse Events</u></p> <p>This report is based on paid claims. The proposed due date change will likely have a significant impact</p>	<p>CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
52	9/24/2012	PRDVM	<p>The HPMS Findings Data Collection Form when exported to Excel is difficult to review and analyze. The multiple merged cells make it difficult to filter or compare the data to accurately ensure the data findings were entered correctly. To be able to quickly and accurately compare data findings we are recommending CMS provide a flat report export which will export the data with all data for specific Standard/Sub-Standard Id's and Measure Specific Criteria Id combinations to fall within one row. The descriptions, although lengthy, would also fall into one cell within the specified row. By expanding the one cell one would be able to see the full description. Where some descriptions are further broken out by Data Element by merging cells, we recommend these fall under their own row with repeated Standard/Sub-Standard Id's and Measure Specific Criteria IDs. This will allow filtering as well as creating simple v-lookups to compare data. This also gives us the capability to upload into an Access database for further analysis to perform additional data checks for accuracy and also to look at year over year changes once the findings are final.</p>	<p>Thank you for your comment. The HPMS team will research this comment and consider this recommendation for future versions of the HPMS Findings Data Collection Form.</p>	N/A
53	9/24/2012	N/A	<p>We recommend that CMS remove the 3/31 resubmission deadline to allow Plans every opportunity to provide CMS with correct, audited data. In the Medicare Part C and D Reporting Requirements Data Validation Procedure Manual Version 2.0: December 2011, p. 1 it states:</p> <p><i>"The purpose of the independent data validation is to ensure that Part C and Part D organizations (sponsoring organizations) are reporting health and</i></p>	<p>CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program. Unfortunately, at this time the deadline cannot be adjusted.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
			<p><i>drug plan data that are reliable, valid, complete, comparable, and timely. The validated data improves reporting and provides CMS with assurance that data are credible and consistently collected and reported by Part C and Part D sponsoring organizations. CMS uses these reported data to respond to inquiries from Congress, oversight agencies, and the public about an organization's performance."</i></p> <p>Accuracy of reported data is critical to CMS, but the Agency has limited the opportunity for Plans to submit corrected data by imposing a 3/31 resubmission deadline. In many cases, this deadline is 30 days from the original submission deadline. Given the complexity of Part C and D reporting where data is extracted from a number of enormous systems (such as claims, care coordination, enrollment, etc.), there is the potential for process / system issue to have a downstream impact on reporting data. Controls are in place to identify and resolve these issues quickly, but there may be instances where the data cannot be rerun and resubmitted before the start of the audit on April 1st. Similar to HEDIS auditing, Plans should have the opportunity correct relatively minor issues and resubmit the corrected data to CMS during the course of the audit. Systemic issues in which there are many factors that result in accurate data would still be identified since they could not be fixed over the course of an audit. In these cases, the Auditor would alert CMS to an organization's inaccurate data and CMS would not include that data in its public datasets.</p>		

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
54	9/24/2012	Technical Specifications, DV Standards	On page one, the Data Validation Standards indicate that the measure-specific criteria for each measure “are based on the applicable Part C/Part D Reporting Requirements Technical Specifications.” However, we have identified several instances, which are described below, where the Standards appear to be inconsistent with the Technical Specifications. We recommend that CMS review the Standards and the Part C and Part D Technical Specifications for consistency and revise the documents as needed.	CMS thanks you for your comment and will consider this feedback as we continue to improve the processes and procedures associated with the Medicare Part C and Part D Data Validation program.	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
55	9/24/2012	Technical Specifications, DV Standards	<p>PLAN OVERSIGHT OF AGENTS - PART C:</p> <p>MSC-9e MSC-9f</p> <p>CMS is proposing to revise this section of the Data Validation Standards by adding two exclusions to Data Element 9, "Organization accurately calculates the number of "agent assisted enrollments" during the applicable reporting period." Specifically, CMS is proposing to add item e., "Excludes enrollments that became effective during the reporting period that were assisted by agents terminated prior to the reporting period" and item f., "Excludes agent assisted enrollments that involve only a member's change from one benefit package to another within the same contract." However, these exclusions are not included in the corresponding Data Element in the Part C Reporting Requirements Technical Specifications Document. (See Data Element 12.6, page 33). AHIP recommends that CMS resolve this inconsistency between the Standards and the Part C Reporting Requirements Technical Specifications. We note that we have identified a similar issue with the corresponding Part D Data Validation Standards and the related Part D Reporting Requirements Technical Specifications, which is discussed below.</p>	<p>Measure-specific criteria 4c and 9e have been removed from the Data Validation Standards to remove ambiguity. Data related to terminated agents should not be excluded from the counts submitted to CMS for the Plan Oversight of Agents measure.</p> <p>In addition, the following clarification exists in the updated version of the Part C Technical Specifications, expected to be released by October 2012:</p> <p>"If a member switches enrollment from one benefit package to another, within the same contract, and uses the services of a licensed agent, this does not count as an agent-assisted enrollment for reporting of element 12.6."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
56	9/24/2012	Technical Specifications, DV Standards	<p>COVREAGE DETERMINATIONS & EXCEPTIONS:</p> <p>MSC-7a</p> <p>Item a. under Element 7 of this measure indicates that the number of reported coverage determinations and exceptions must include “all coverage determinations/exceptions with a date of receipt that occurs during the reporting period, regardless of when the final decision was made.” (Emphasis added.) This instruction appears to be inconsistent with the corresponding section of the Part D Reporting Requirements Technical Specifications, which states that requests “for coverage determinations and exceptions should be reported based on the decision date” (emphasis added) and notes that this is a change from the prior year’s specifications. (See Data Element E., page 52.) AHIP recommends that CMS resolve the inconsistency between the Standards and the Part D technical specifications.</p>	MSC-7a has been updated to correctly state "date of decision."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
57	9/24/2012	Technical Specifications, DV Standards	<p>PLAN OVERSIGHT OF AGENTS (PART D):</p> <p>MSC-9e MSC-9f</p> <p>As noted above, CMS is proposing to revise this section of the Data Validation Standards in the same manner as the comparable Part C data element, by adding the two exclusions, item e. and item f. to Data Element 9, "Organization accurately calculates the number of "agent assisted enrollments" during the applicable reporting period." The proposed exclusions are not reflected in the corresponding Data Element in the Part D Reporting Requirements Technical Specifications Document (See Data Element F, page 73). AHIP recommends that CMS resolve this inconsistency between the Standards and the Part D Reporting Requirements Technical Specifications.</p>	<p>Measure-specific criteria 4c and 9e have been removed from the Data Validation Standards to remove ambiguity. Data related to terminated agents should not be excluded from the counts submitted to CMS for the Plan Oversight of Agents measure.</p> <p>In addition, the following clarification exists in the updated version of the Part C Technical Specifications, expected to be released by October 2012:</p> <p>"If a member switches enrollment from one benefit package to another, within the same contract, and uses the services of a licensed agent, this does not count as an agent-assisted enrollment for reporting of element 12.6."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
58	9/21/2012	DV Standards, FDCF	<p>PLAN OVERSIGHT OF AGENTS (PARTS C & D):</p> <p>MSC-4c</p> <p>The drafted DV standards have introduced a new criteria for DV for element 12.1 as follows: 4c. Excludes Agents who were terminated during the applicable reporting period. This new DV criteria does not parallel the Technical Specifications.</p> <p>Is the new 12.1 criteria, perhaps, a typo, in that the intent was to say, 4c. For other organization types, please report this reporting section under the appropriate section in the Part D reporting requirements. For example, MA-PDs should report in Part D for this reporting section, listed as a “section” in Part D. Our suspicion that the word “during” is a typo is confirmed by inspection of DV standard 12.5, Organization accurately calculates the number of agents whose selling privileges were revoked by the organization based on conduct or discipline, including the following criteria:</p> <ul style="list-style-type: none"> a. Includes all agents with revocations initiated during the applicable reporting period, regardless of when the conduct causing the revocation occurred. b. The number calculated for Data Element 12.5 is a subset of the total number of agents calculated for Data Element 12.1. <p>[Data Element 12.5]</p> <p>An impossible situation is created by the requirement not report terminated agents in 12.1 and then to report on a null situation in 12.5.</p> <p>If not a typo and actually an intended change, this new DV criteria changes the approach to 12.6 (Is CMS asking that enrollments due to terminated-during-the-year agents be removed from 12.6?):</p> <p>9d. Includes enrollments that are as a direct result of</p>	<p>Measure-specific criteria 4c and 9e have been removed from the Data Validation Standards to remove ambiguity. Data related to terminated agents should not be excluded from the counts submitted to CMS for the Plan Oversight of Agents measure.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
59	9/21/2012	Supporting Statement	<p>Based on the proposed changes in 508Supporting Statement_DataValidation_20120625.pdf as well as proposed commentary in the Federal Register Vol 77 No 130, please confirm/correct the items below, assuming the proposed changes become final, for the next Data Validation cycle:</p> <p>PROCEDURE FREQUENCY: 1. Will not undergo data validation review for CYs 2011 - 2013. 2. Will CMS collect this measure through HPMS for CYs 2012 - 2013?</p> <p>PROVIDER NETWORK ADEQUACY: 1. Will not undergo data validation review for CYs 2012 - 2013. 2. Will CMS collect this measure through HPMS for CYs 2012 - 2013?</p> <p>EMPLOYER GROUP PLAN SPONSORS: 1. Will not undergo data validation review for CYs 2012 - 2013. 2. Will CMS collect this measure through HPMS for CYs 2012 - 2013?</p> <p>R/HI/LTC PHARMACY ACCESS: 1. Will not undergo data validation review for CYs 2012 - 2013. 2. Elements A&B have already been submitted to CMS for CY 2012. Will elements C&D still be collected for CY 2012? 3. Will CMS collect this measure through HPMS for CY 2013?</p>	<p>Please CMS's responses to each inquiry, as follows:</p> <p>PROCEDURE FREQUENCY: 1. Will not undergo data validation review for CYs 2011 - 2013. - CONFIRMED 2. Will CMS collect this measure through HPMS for CYs 2012 - 2013? - 2012: Yes, 2013: No</p> <p>PROVIDER NETWORK ADEQUACY: 1. Will not undergo data validation review for CYs 2012 - 2013. - CONFIRMED 2. Will CMS collect this measure through HPMS for CYs 2012 - 2013? - 2012: Yes, 2013: No</p> <p>EMPLOYER GROUP PLAN SPONSORS: 1. Will not undergo data validation review for CYs 2012 - 2013. - CONFIRMED 2. Will CMS collect this measure through HPMS for CYs 2012 - 2013? - 2012: Yes, 2013: Yes</p> <p>R/HI/LTC PHARMACY ACCESS: 1. Will not undergo data validation review for CYs 2012 - 2013. - CONFIRMED</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
				<p>2. Elements A&B have already been submitted to CMS for CY 2012. Will elements C&D still be collected for CY 2012? - Yes</p> <p>3. Will CMS collect this measure through HPMS for CY 2013? - Yes</p>	
60	9/21/2012	DV Standards, FDCF	<p>SRAEs:</p> <p>MSC-5a</p> <p>Typo Issue: The Standard reads - “MSC-5a: Accurately maps SRAEs to the codes provided by CMS in Appendix 5 of the Part C Reporting Requirements Technical Specifications Document, Table 2.”</p> <p>Burchfield’s suggested clarification - “MSC-5a: Accurately maps SRAEs to the codes provided by CMS in Appendix 2 of the Part C Reporting Requirements Technical Specifications Document, Table 2.”</p>	This correction has been made to the measure-specific criteria.	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
61	9/21/2012	DV Standards, FDCF	<p>SRAEs:</p> <p>MSC-6a</p> <p>Typo Issue: The Standard reads “MSC-6a: Accurately maps HACs to the codes provided by CMS in Appendix 2 of the Part C Reporting Requirements Technical Specifications Document, Table 3.”</p> <p>Burchfield’s suggested clarification “MSC-6a: Accurately maps HACs to the codes provided by CMS in Appendix 2 of the Part C Reporting Requirements Technical Specifications Document, Table 3 and Table 4”</p>	This correction has been made to the measure-specific criteria.	N/A
62	9/21/2012	DV Standards, FDCF	<p>SRAEs:</p> <p>MSC-7a</p> <p>Typo Issue The Standard reads “MSC-7a: Accurately maps HACs to the codes provided by CMS in Appendix 52 of the Part C Reporting Requirements Technical Specifications Document, Table 4.”</p> <p>Burchfield’s suggested clarification “MSC-7a: Accurately maps HACs to the codes provided by CMS in Appendix 52 of the Part C Reporting Requirements Technical Specifications Document, Table 4.”</p>	This correction has been made to the measure-specific criteria.	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
63	9/21/2012	DV Standards, FDCF	<p>MTM:</p> <p>MSC-12c</p> <p>Typo Issue: The Standard reads “MSC-12c: Properly identifies and includes the number of changes to drug therapy made as a result of MTM program interventions within the reporting period for each applicable member (includes, but is not limited to, dosage changes, therapeutic or generic substitutions, and discontinuation or addition of therapy). [Note to reviewer: If the change occurred in the calendar year after the current reporting period, but was the result of an intervention made within the current reporting period, the change may be reported for the current reporting period.] [Data Elements O – Q]”</p> <p>Burchfield’s suggested clarification “<u>MSC-10c</u>: Properly identifies and includes the number of changes to drug therapy made as a result of MTM program interventions within the reporting period for each applicable member (includes, but is not limited to, dosage changes, therapeutic or generic substitutions, and discontinuation or addition of therapy). [Note to reviewer: If the change occurred in the calendar year after the current reporting period, but was the result of an intervention made within the current reporting period, the change may be reported for the current reporting period.] [<u>Data Elements Q – S</u>]”</p>	The updated version of the Part D Technical Specifications, expected to be published by October 2012 includes updated data element designations, which align correctly with the measure-specific criteria in the Data Validation Standards.	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
64	9/21/2012	DV Standards, FDCF	<p>MTM:</p> <p>MSC-9a & 9b</p> <p>Typo Issue and Burchfield's suggested clarification: MSC 9a and MSC 9b should be for marked as applicable for data elements N, O, P. Currently just element N is marked as applicable, yet the description states "Organization accurately identifies data on CMR dates", clearly implying the MSCs should apply to all CMR date-related elements.</p>	<p>The updated version of the Part D Technical Specifications, expected to be published by October 2012 includes updated data element designations, which align correctly with the measure-specific criteria in the Data Validation Standards.</p>	N/A
65	9/21/2012	FDCF	<p>GRIEVANCES (PART C):</p> <p>MSC-6</p> <p>Typo Issue: The Standards read "Properly sorts the total number of grievances by grievance category Fraud; Enrollment/Disenrollment; Benefit Package; Access; Marketing; Customer Service; Privacy Issues; Quality of Care; and Appeals. [<u>Data Elements 5.1-5.5.10</u>]"</p> <p>Burchfield's suggested clarification: "Properly sorts the total number of grievances by grievance category Fraud; Enrollment/Disenrollment; Benefit Package; Access; Marketing; Customer Service; Privacy Issues; Quality of Care; and Appeals. [<u>Data Elements 5.1-5.10</u>]"</p>	<p>This correction has been made to the measure-specific criteria in the FDCF.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
66	9/21/2012	DV Standards, FDCF	<p>COVERAGE DETERMINATIONS & EXCEPTIONS:</p> <p>MSC-8d</p> <p>Guidance Issue: Measure Specific Criteria 8d (pg. 40) states, "Includes PA requests that were approved soon after the adjudication timeframes expired (i.e., within 24 hours) and were not auto-forwarded to the IRE." So, for element C, requests approved soon after the timeframe expired (and not sent to the IRE) should be included (as Chapter 18 allows this grace period). Are these requests considered timely, and as such be reported in element D as well? In addition, if they're approved, should they be reported in element E as well?</p> <p>Burchfield's suggested clarification:</p> <p>i. If CMS considers such PA decisions as non-timely for this reporting, it would be helpful to explicitly state as such in MSCs 9 and 10. For example, insert the following into MSCs 9 & 10 "Excludes PA requests that were approved soon after the adjudication timeframes expired (i.e., within 24 hours) and were not auto-forwarded to the IRE."</p> <p>ii. Alternatively, if CMS considers such PA decisions as timely for this reporting, it would be helpful to explicitly state as such in MSCs 9 and 10. For example, insert the following into MSCs 9 & 10 "Includes PA requests that were approved soon after the adjudication timeframes expired (i.e., within 24 hours) and were not auto-forwarded to the IRE."</p>	<p>The following statement exists in the June 2012 version of the Part D Technical Specifications:</p> <p>"Cases that were approved (fully favorable to the enrollee) soon after the adjudication timeframe expire (i.e., within 24 hours) and were not auto-forwarded to the IRE should be included in elements C, F, I and L, but should be excluded from elements D, G, J, and M."</p> <p>1. The answer to the first question ("Are these requests considered timely, and as such be reported in element D as well?") is no.</p> <p>2. The answer to the second question ("In addition, if they're approved, should they be reported in element E as well?") is yes, the updated version of the Part D Technical Specifications specifies that decisions "made by the plan" are to be included for Elements E, H, K, and N, which includes those cases that were approved (fully favorable to the enrollee) soon after the adjudication timeframe expire (i.e., within 24 hours) and were not auto-forwarded to the IRE.</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
67	9/21/2012	DV Standards, FDCF	<p>COVERAGE DETERMINATIONS & EXCEPTIONS:</p> <p>MSC-7a</p> <p>Guidance Issue: Measure Specific Criteria 7a (pg. 39) states, "Includes all coverage determinations/exceptions with a date of receipt that occurs during the reporting period, regardless of when the final decision was made." However, Measure Specific Criteria 8a (pg. 40) states "Includes all PA decisions made (both favorable and unfavorable) with a date of decision that occurs during the reporting period." Similarly, later Measure Specific Criteria (i.e. for elements D - N) all use language with some variation on the requirement of reporting based on the date of decision.</p> <p>Burchfield's suggested clarification: To better align with the Technical Specifications, we recommend removing MSC 7a (i.e., it seems likely the intent is to have plans report based on date of decision, not date of receipt).</p>	MSC-7a has been updated to correctly state "date of decision."	N/A
68	9/21/2012	DV Standards, FDCF	<p>REDETERMINATIONS:</p> <p>MSC-5c & 5i</p> <p>Guidance Issue: The Redeterminations specifically states two MSCs related to IRE activity:</p> <p>i. "Includes redetermination requests that were forwarded to the IRE because the organization failed to make a timely decision." MSC 5c</p> <p>ii. "Excludes IRE decisions, as they are considered to be the second level of appeal". MSC 5i</p>	The Coverage Determinations and Exceptions measure-specific criteria have been updated to include the following language for Elements E, H, K, and N: "Excludes decisions made by the IRE." In addition, the Part D Technical Specifications have been updated to specify that only those decisions "made by the plan" are to be included in the counts for Elements E, H, K, and N.	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
			<p>Clearly, plans should count redetermination requests received by the plan, yet forwarded to the IRE if the plan did not meet the timely decision requirement. However, plans should exclude the actual decision made by the IRE from reporting.</p> <p>Coverage Determinations/Exceptions does have IRE language for elements C, D, F, G, I, J, L, and M. Elements C, F, I, and L all have MSCs stating “Includes [exception type] requests that were forwarded to the Independent Review Entity (IRE) because the organization failed to make a timely decision.” Additionally, elements D, G, J, and M all have MSCs stating “Excludes [exception type] requests that were forwarded to the IRE because the organization failed to make a timely decision.” However:</p> <p>a. There is no Coverage Determinations/Exceptions element with language similar to Redeterminations MSC 5i.</p> <p>b. Additionally, elements E, H, K, and N have no IRE language at all. Each of these introduces reporting ambiguity.</p> <p>Burchfield’s suggested clarification: A simple fix to remove both ambiguities:</p> <p>i. For elements C – N: introduce an MSC for each element similar to Redeterminations MSC 5i: “Excludes IRE decisions, as they are considered to be the second level of determination.”</p>		
69	9/21/2012	DV Standards, FDCF	COVERAGE DETERMINATIONS & EXCEPTIONS:	The phrase "enhanced alternative drugs" has been removed from MSC-5d and updated to state: "Excludes	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
			<p>MSC-5d</p> <p>Guidance Issue: MSC 5d reads "Excludes pharmacy transactions for excluded drugs and enhanced alternative drugs." However, this language is not repeated for any elements C - N, leading to ambiguity around whether plans should include excluded products in the counts for UM decisions.</p> <p>Burchfield's suggested clarification:</p> <p>i. If the intent is to never have plans report excluded and EA drugs in any element C - N of the report, we recommend explicitly adding in as an MSC for each element.</p> <p>ii. Alternatively, if the intent is to allow plans to report such products in any elements C - N, leave the language as-is.</p>	<p>pharmacy transactions for excluded drug categories."</p> <p>In addition, MSC-7g has been updated to read: "Excludes coverage determinations/ exceptions regarding excluded drug categories."</p>	
70	9/21/2012	DV Standards, FDCF	<p>COVERAGE DETERMINATIONS & EXCEPTIONS:</p> <p>MSC-9b</p> <p>Guidance Issue: MSC 9b reads "Excludes favorable determinations in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines..." There is similar language in MSCs for elements G, J, and M. This is the first time appearance of the words payment dispute in the Measure Standards, and we want to be sure we understand the intention. Certainly, an enrollee's dispute about payment is a coverage determination (per Chapter 18). Now, the specific mention of excluding non-timely payment dispute decisions from Element D seems to imply that timely payment dispute decisions should be</p>	<p>Please note that the Part D Technical Specifications state: "A coverage determination is timely only when the sponsor makes a decision and appropriately notifies the enrollee of the decision within the applicable adjudication timeframe. For approvals, sponsors must also authorize or provide the benefit (<u>or payment</u>) under dispute within the applicable adjudication timeframe. Sponsors should refer to Chapter 18, Sections 40, 50, and 130 of the Prescription Drug Benefit Manual." For this reporting, coverage determinations should encompass any payments that fall into one of the specified reporting categories. Any</p>	N/A

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			<p>included in Element D, and both timely and non-timely payment dispute decisions should be included in Element C. A similar explanation applies to all other elements F –N.</p> <p>However, consider the following clarification about payment disputes previously received from CMS, which states payment disputes should not be included in any elements except Element A:</p> <p>(email to CMS on 2/15/2012) "Hi Part D Plan Reporting, Suppose a member fills a prescription at an out-of-network pharmacy (for example, they were on vacation and not near any network pharmacies). The pharmacy charges them a higher copay than they're used to, and they file a request to be reimbursed by the plan. Per Chapter 18, these are coverage determinations. However, suppose the drug was a generic drug, available on the plan's formulary, and is a drug the member regularly receives. In other words, this coverage determination request isn't really a UM-related exception (i.e. it's not a non-formulary, or tiering exception, etc.). Certainly, the member's fill will constitute a "pharmacy transaction", so it will be reported in element A of this report (total pharmacy transactions). However, should this particular determination scenario (direct member reimbursement, but unrelated to PA or UM exceptions) also be reported in any element C – J of this report, and if so, which element?"</p> <p>(response from CMS on 2/24/2012) "No, this particular scenario would not be reported in</p>	<p>payments that do not fall into one of the specified reporting categories should not be reported in this reporting section.</p>	

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			<p>any other element besides element A."</p> <p>Burchfield's suggested clarification:</p> <p>i. If the intent is for plans to include payment disputes in all elements C – N as applicable, we recommend adding a similar clarification to element C – N's MSCs, so there is no ambiguity. This way it will be clear to plans that payment disputes should be included, as applicable, in elements C – N.</p> <p>ii. Alternatively, if the previous email clarification is still the recommended course of action (i.e., payment related disputes should not appear in any elements C – N), we recommend removing the references to the words payment disputes in elements C – N.</p>		
71	9/21/2012	FDCF	<p>MTM:</p> <p>Standards 2e & 3a</p> <p>Typo Issue: Sections 2.e and 3.a have scoring up to "Data Element J" and continue to contain "Section II".</p> <p>Burchfield's suggested clarification:</p> <p>i. Data elements should go up to "Data Element S", based on the new DV Measure Standards.</p> <p>ii. Additionally, "Section II" is no longer identified as such in the DV Measure Standards: recommend removal from FDCF</p> <p>iii. Finally, "Data Element A" is no longer present in the new DV Measure Standards: recommend removing from the FDCF <i>or</i> recommend "re-numbering" the DV Measure Standards</p>	<p>The updated version of the Part D Technical Specifications, expected to be published by October 2012 will include updated data element designations, which align correctly with the measure-specific criteria in the FDCF. In addition, "Section II" and the "Data Element A" cell have been removed from Column E in the FDCF.</p>	N/A

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72	9/21/2012	FDCF	MTM: MSC-9a & 9b Typo Issue and Burchfield's suggested clarification: MSC 9a and MSC 9b should be present for data elements N, O, P	The updated version of the Part D Technical Specifications, expected to be published by October 2012 will include updated data element designations, which align correctly with the measure-specific criteria in the FDCF.	N/A
73	9/21/2012	FDCF	MTM: MSC-10a, 10b, & 10c Typo Issue and Burchfield's suggested clarification: MSC 10a, MSC10b, and MSC10c should be present for data elements Q, R, S	The updated version of the Part D Technical Specifications, expected to be published by October 2012 will include updated data element designations, which align correctly with the measure-specific criteria in the FDCF.	N/A
74	9/21/2012	FDCF	COVERAGE DETERMINATIONS & EXCEPTIONS: Standards 2e & 3a Typo Issue and Burchfield's suggested clarification: Sections 2.e and 3.a scoring goes up to "Data Element J". However, it seems the data elements should go up to "Data Element N", based on the new DV Measure Standards.	The scoring (column E) in the FDCF for Standard 2e has been corrected in the updated version of the FDCF. In addition, the scoring for Standard 3a has been corrected to include Elements K - N.	N/A
75	9/21/2012	FDCF	REDETERMINATIONS: Typo Issue: The Findings Data Collection Form does not have Data Element "D". Burchfield's suggested clarification: Add Element D.	The scoring (column E) in the FDCF for Standards 2a and 2e has been corrected in the updated version of the FDCF.	N/A
76	9/26/2012	DV Standards, FDCF	DV Standard 1c Currently, the Standard reads: "Source documents are error-free (e.g., programming code and	Data Validation Standard 1c, changed: "Source documents are error-free	N/A

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			<p>spreadsheet formulas have no messages or warnings indicating errors)”</p> <p>Comment: This standard for 2013 (unchanged since 2011) remains unclear and not useful to validation of the programming code. There are many times, where programming code will not throw an error, warning or other message, but it remains in-fact wrong in pulling the correct data from many stand points, for example:</p> <ol style="list-style-type: none"> 1. The code’s select statements pulls from the wrong or incomplete fields 2. The codes select statement uses WHERE or ORDERBY clauses which produce inaccurate results (e.g. when the code for pulling enrollment records to calculate Member Months in MTMP chooses enrollment records based the last record modified according to record time stamp as the most current record for an enrollee, compared to pulling the selecting the most current “open” enrollment period.) 3. The code pulls records with nulls in fields and so on, so this Standard will not address basic coding errors. <p>ACG recommends that CMS modify this Standard to read: “Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection etc.)”</p>	<p>(e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors).”</p> <p>TO:</p> <p>“Source documents are error-free (e.g., programming code and spreadsheet formulas have no messages or warnings indicating errors, use correct fields, have appropriate data selection etc.)”</p>	

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77	9/26/2012	DESI	<p>Section 3.3 Requirement for Extraction and Review of Source Data – Exhibit 5:</p> <p>ACG recommends the following changes to the examples of source data to review</p> <p>i. Part C and Part D Grievances: ACG recommends that reviewers also review case notes from Grievances to assure proper categorization; case notes can be included in the data sample pulled from systems.</p> <p>ii. MTMP: ACG notes that Claims files will NOT confirm medication reviews or prescriber interventions (prescriber letters or other communications will,) it can only confirm changes to drug therapy.</p> <p>iii. Coverage Determinations: Similar to Part C and Part D Grievances, ACG recommends the inclusion of Coverage Determination Case Notes in the recommended source data review (this can be included in data sample pulls by most plans and PBMs). These case notes are typically the only way to determine if by example i) the Plan/PBM includes PA exceptions in the exceptions reports and ii) formulary exceptions were properly reported in the right reporting category.</p>	<p>Case notes have been added as a source data example for Grievances and Coverage Determinations.</p> <p>Regarding the references to medication reviews and prescriber interventions, CMS agrees and therefore has revised the source data examples to:</p> <p>1 - Remove references of confirming medication reviews and prescriber interventions with claims files.</p> <p>2 - Include evidence of communication (i.e. prescriber letters) which can be used to confirm medication reviews and prescriber interventions.</p>	N/A

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78	9/26/2012	DESI	<p>Section 3.4 Evaluating the Data:</p> <p>For 2013 CMS adds the following to the instructions: “including the number of errors found when examining the source data”</p> <p>ACG recommends that CMS change this statement to read “including the number and percentage of errors or variance from HPMS filed data found when examining the source data.” This more clearly ties the results of the sampling to CMS’ standard of pass or fail to 10% variance in the sample to the reported data.</p>	<p>Changed:</p> <p>“including the number of errors found when examining the source data.”</p> <p>TO:</p> <p>“including the number and percentage of errors or variance from HPMS filed data found when examining the source data.”</p>	N/A
79	9/26/2012	DV Standards, FDCF	<p>GRIEVANCES (PART D):</p> <p>MSC-5g</p> <p>Medicare Part D Technical Specifications for 2012, page 44, VII-E: In section E. Notes, the 4th bullet clarifies that withdrawn grievances should be excluded from reporting.</p> <p>Questions and Request for Clarification:</p> <p>For the identification of grievance withdrawals, why would it apply to Part D and not Part C? The difference between Part C and Part D grievance regulations is minimal and there should be no reason for one and not the other.</p> <p>Also, why is there a special change for grievance withdrawal when such a provision does not exist in the regulations? ACG strong believes that the exclusion of grievance withdrawals has the potential of causing confusion in the market.</p>	<p>The Part C Technical Specifications and measure-specific criteria will be updated to exclude withdrawn Part C grievances for the 2013 reporting year.</p>	N/A

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80	9/26/2012	DV Standards, FDCF	<p>SNP:</p> <p>MSC-6a</p> <p>6. "Organization accurately calculates the number of initial assessments performed on new members, including the following criteria:</p> <p style="padding-left: 20px;">a. Includes all initial assessments that were completed (within 90 days of enrollment) confirmed actually occurred during a previous reporting period (even if the event occurred during the reporting period).</p> <p>ACG requests CMS to clarify if the "within 90 days of enrollment" can include both 90 days prior to enrollment as well as 90 days after enrollment?</p> <p>Rationale: During AEP, Plans can receive Notice of Enrollment letters in October for members that will be effective January 1, 201x. The Notice period during AEP can be 90 days. Some Plans have assessment programs where contact is initiated with the enrollees as soon as the Notice of Enrollment is received. This contact would occur prior to the effective date of enrollment. The purpose of the contact is to promote seamless transitional care and it would seem appropriate to count these assessments.</p>	<p>The language "Includes all initial assessments that were completed (within 90 days of enrollment)" refers only to the time period (90 days) after the member enrolls with the plan.</p>	N/A

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81	8/10/2012	DV Standards, FDCF	SRAE, DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A
82	8/10/2012	DV Standards, FDCF	SRAE: Move MSC from 4b to 4a, where it is more applicable.	<p>MSC-4a, changed:</p> <p>"Includes all surgeries with dates of service that occur during the reporting period."</p> <p>TO:</p> <p>"Includes all surgeries with dates of service that occur during the reporting period. If a date of service is not available, date of discharge is acceptable."</p>	N/A

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83	8/10/2012	DV Standards, FDCF	SRAE: Move MSC from 4b to 4a, where it is more applicable.	<p>MSC-4b, changed:</p> <p>"Includes only surgeries that occur in an acute inpatient hospital setting. If a date of service is not available, date of discharge is acceptable"</p> <p>TO:</p> <p>"Includes only surgeries that occur in an acute inpatient hospital setting."</p>	N/A
84	8/10/2012	DV Standards, FDCF	SRAE, MSC-5b: Update to maintain consistency with the guidance in the 2011 tech specs: "if a report by date of service is not practical or possible then a report by discharge date is acceptable."	<p>MSC-5b, changed:</p> <p>"Includes all specified SRAEs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period).</p> <p>TO:</p> <p>"Includes all specified SRAEs that are confirmed during the reporting period. If date of service is not available, date of discharge is acceptable.</p>	N/A
85	8/10/2012	DV Standards, FDCF	SRAE: MSC-5e was originally incorporated in response to the statement in the 2010 tech specs: "If an SRAE event is alleged to have occurred in a previous reporting period but you do not receive a credible report until a later reporting period, you report the event in the later reporting period. In other words report them via HPMS as you become aware of confirmed SRAE events." This statement has since been removed from the tech specs; remove it from the MSC.	<p>MSC-5e, deleted:</p> <p>"Includes any supplemental information provided by the hospital regarding SRAEs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period)."</p>	N/A

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86	8/10/2012	DV Standards, FDCF	SRAE: Update to maintain consistency with the guidance in the 2011 tech specs: "if a report by date of service is not practical or possible then a report by discharge date is acceptable."	<p>MSC-6b, changed:</p> <p>"Includes all specified HACs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period). The diagnosis code and procedure code may be on the same claim or on different claims, and may or may not be on the same date of service."</p> <p>TO:</p> <p>"Includes all specified HACs that are confirmed during the reporting period. If date of service is not available, date of discharge is acceptable. The diagnosis code and procedure code may be on the same claim or on different claims, and may or may not be on the same date of service."</p>	N/A
87	8/10/2012	DV Standards, FDCF	SRAE: MSC-6f was originally incorporated in response to the statement in the 2010 tech specs: "If an SRAE event is alleged to have occurred in a previous reporting period but you do not receive a credible report until a later reporting period, you report the event in the later reporting period. In other words report them via HPMS as you become aware of confirmed SRAE events." This statement has since been removed from the tech specs; remove it from the MSC.	<p>MSC-6f, deleted:</p> <p>"Includes any supplemental information provided by the hospital regarding HACs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period)."</p>	N/A

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88	8/10/2012	DV Standards, FDCF	SRAE, MSC-7b: Update to maintain consistency with the guidance in the 2011 tech specs: "if a report by date of service is not practical or possible then a report by discharge date is acceptable."	<p>MSC-7b, changed:</p> <p>"Includes all specified HACs that are confirmed during the reporting period (even if the event actually occurred during a previous reporting period). The diagnosis code and procedure code may be on the same claim or on different claims, and may or may not be on the same date of service."</p> <p>TO:</p> <p>"Includes all specified HACs that are confirmed during the reporting period. If date of service is not available, date of discharge is acceptable. The diagnosis code and procedure code may be on the same claim or on different claims, and may or may not be on the same date of service."</p>	N/A
89	8/10/2012	DV Standards, FDCF	SRAE: Move "or date of discharge, if date of service is unavailable" from MSC-7e to 7b, where it is more applicable.	<p>MSC-7e, changed:</p> <p>"For Data Element 3.18, includes SSI diagnosis codes with a date of service (or date of discharge, if date of service is unavailable) that extends 30 days from the date of service."</p> <p>TO:</p> <p>"For Data Element 3.18, includes SSI diagnosis codes with a date of service that extends 30 days from the date of service."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
90	8/10/2012	DV Standards, FDCF	SRAE: Move "or date of discharge, if date of service is unavailable" from MSC-7f to 7b, where it is more applicable.	<p>MSC-7e, changed:</p> <p>"For Data Element 3.19, includes SSI diagnosis codes with a date of service (or date of discharge, if date of service is unavailable) that extends 30 days from the date of service."</p> <p>TO:</p> <p>"For Data Element 3.19, includes SSI diagnosis codes with a date of service that extends 30 days from the date of service."</p>	N/A
91	8/10/2012	DV Standards, FDCF	SRAE: Move "or date of discharge, if date of service is unavailable" from MSC-7g to 7b, where it is more applicable.	<p>MSC-7e, changed:</p> <p>"For Data Element 3.20, includes SSI diagnosis codes with a date of service (or date of discharge, if date of service is unavailable) that extends 30 days from the date of service."</p> <p>TO:</p> <p>"For Data Element 3.20, includes SSI diagnosis codes with a date of service that extends 30 days from the date of service."</p>	N/A

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92	8/10/2012	DV Standards, FDCF	Grievances (Part C): Add guidance to reflect updated policy clarification on aggregating quarterly data before applying 90% threshold.	<p>Added the following two statements to the header information for Part C Grievances:</p> <p>"Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold."</p> <p>"Note to reviewer: Apply the 90% threshold to the total count of grievances calculated. Do not apply the 90% threshold to individual grievance categories."</p>	N/A
93	8/10/2012	DV Standards, FDCF	Grievances (Part C), DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
94	8/10/2012	DV Standards, FDCF	Grievances (Part C), MSC-4: Add the word "improperly" to make it consistent in the Part D Grievance MSC.	MSC-4, changed: "Requests for organization determinations or appeals are not categorized as grievances." TO: "Requests for organization determinations or appeals are not improperly categorized as grievances."	N/A
95	8/10/2012	DV Standards, FDCF	Grievances (Part C), MSC-5: add language to reflect the statement in the updated version of the Part C Technical Specifications: "Report grievances if the member is ineligible on the date of the call to the plan but was eligible previously."	Added MSC-5b: "Includes all grievances reported by or on behalf of members who were previously eligible, regardless of whether the member was eligible on the date that the grievance was reported to the organization."	N/A
96	8/10/2012	DV Standards, FDCF	Grievances (Part C), MSC-5: Remove "under the applicable grievance category" because the purpose of this MSC is to ensure multiple issues are recorded as separate grievances. The correct categorization of each of those issues should be verified by MSC-6.	MSC-5c, changed: "If a grievance contains multiple issues filed under a single complainant, each issue is calculated as a separate grievance under the applicable grievance category." TO: "If a grievance contains multiple issues filed under a single complainant, each issue is calculated as a separate grievance."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
97	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations: Add guidance to reflect updated policy clarification on aggregating quarterly data before applying 90% threshold.	Added the following statement to the header information for Organization Determinations / Reconsiderations: "Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold."	N/A
98	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations, DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	DV Standard 1a, changed: "Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS." TO: "Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
99	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations, MSC-4b: Prior authorization requests are organization determinations and therefore covered by MSC-4a. Remove "and prior authorization requests if applicable, regardless of when the request was received." This will keep MSC-4b focused solely on adjudicated claims.	MSC-4b, changed: "Includes adjudicated claims with a date of adjudication that occurs during the reporting period and prior authorization requests if applicable, regardless of when the request was received. " TO: "Includes adjudicated claims with a date of adjudication that occurs during the reporting period."	N/A
100	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations: consolidate MSC-7b and MSC-7c into one MSC.	MSC-7b, changed: "Includes all adverse payment (claim) organization determinations that result in zero payment being made to non-contract providers." TO: "Includes all adverse payment (claim) organization determinations that result in zero payment being made to contract and non-contract providers."	N/A
101	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations: consolidate MSC-7b and MSC-7c into one MSC.	MSC-7c, deleted: "Includes all adverse payment (claim) organization determinations that result in zero payment being made to contract providers/suppliers."	N/A

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102	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations, MSC-10c: remove this MSC as CMS is no longer differentiating between contract and non-contract providers.	MSC-10c, deleted: "Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service."	N/A
103	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations, MSC-11c: remove this MSC as CMS is no longer differentiating between contract and non-contract providers.	MSC-11c, deleted: "Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service."	N/A
104	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations: consolidate MSC-12b and MSC-12c into one MSC.	MSC-12b, changed: "Includes all adverse payment (claim) reconsideration determinations that result in zero payment being made to non-contract providers." TO: "Includes all adverse payment (claim) reconsideration determinations that result in zero payment being made to contract and non-contract providers."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
105	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations: consolidate MSC-12b and MSC-12c into one MSC.	MSC-12c, deleted: "Includes all adverse payment (claim) reconsideration determinations that result in zero payment being made to contract providers/suppliers."	N/A
106	8/10/2012	DV Standards, FDCF	Organization Determinations / Reconsiderations, MSC-12d: remove this MSC as CMS is no longer differentiating between contract and non- contract providers.	MSC-12d, deleted: "Properly defines contract and non-contract providers/suppliers based on whether the provider/supplier is under contract for the plan in which the member is enrolled on the date of service."	N/A
107	8/10/2012	DV Standards, FDCF	Plan Oversight of Agents (Part C), DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	DV Standard 1a, changed: "Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS." TO: "Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
108	8/10/2012	DV Standards, FDCF	Plan Oversight of Agents (Part C), MSC-5a: update in response to #183 in the Part C Industry Questions spreadsheet.	<p>MSC-5a, changed:</p> <p>"Includes all agents with investigations that were completed during the applicable reporting period, regardless of when the complaint was received."</p> <p>TO:</p> <p>"Includes all agents with investigations that were completed during the applicable reporting period, regardless of when the complaint was received and whether the member remained enrolled, disenrolled, or declined enrollment during the enrollment process."</p>	N/A
109	8/10/2012	DV Standards, FDCF	Plan Oversight of Agents (Part C), MSC-5: update in response to #183 in the Part C Industry Questions spreadsheet.	<p>Added MSC-5d:</p> <p>"Excludes investigations in which the member or agent could be not contacted."</p>	N/A
110	8/10/2012	DV Standards, FDCF	Plan Oversight of Agents (Part C), MSC-9c: 800 series plans do not have to report this measure, the additional guidance re: excluding 800-series agent-assisted enrollments is not necessary and may confuse readers. Update accordingly.	<p>MSC-9c, changed:</p> <p>"Includes agent assisted enrollments from both the individual and group enrollment process (excluding 800-series agent assisted enrollments)."</p> <p>TO:</p> <p>"Includes agent assisted enrollments from both the individual and group enrollment process."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
111	8/10/2012	DV Standards, FDCF	SNP, DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A
112	8/10/2012	DV Standards, FDCF	SNP, MSC-5: Assessments in the Part C Technical Specifications are referred to as "health risk assessments." Update MSC-5 to mirror this language.	<p>MSC-5, changed:</p> <p>"Organization accurately calculates the number of members eligible for a reassessment during the reporting period"</p> <p>TO:</p> <p>"Organization accurately calculates the number of members eligible for an annual health risk reassessment during the reporting period"</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
113	8/10/2012	DV Standards, FDCF	MTM, DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A
114	8/10/2012	DV Standards, FDCF	MTM, MSC-7a: Per question ID # 116 in the Part D Industry Questions spreadsheet, update this MSC to align with the new verbiage added to the Notes section in the Part D Technical Specifications: "Sponsors should not count and report a 12/31 disenrollment date as a true opt-out due to disenrollment."	<p>MSC-7a, changed:</p> <p>"Properly identifies and includes members' date of MTM program opt-out that occurs within the reporting period."</p> <p>TO:</p> <p>"Properly identifies and includes members' date of MTM program opt-out that occurs within the reporting period, but prior to 12/31."</p>	N/A
115	8/10/2012	DV Standards, FDCF	MTM, MSC-8c: Remove this as MSC-4 includes verification that the sponsor is defining CMR correctly. This could lead to a no finding in both places for the same mistake.	<p>MSC-8c, deleted:</p> <p>"Includes all spoken conversations, voicemails, messages left on answering machines, or welcome letters that include a clear offer for a CMR."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
116	8/10/2012	DV Standards, FDCF	MTM, MSC-8d: Remove this as MSC-4 includes verification that the sponsor is defining CMR correctly. This could lead to a no finding in both places for the same mistake.	MSC-8d, deleted: "Excludes MTM members who the organization cannot confirm received the offer (e.g., returned mail or incorrect phone numbers)."	N/A
117	8/10/2012	DV Standards, FDCF	MTM, MSC-9b: Remove this as MSC-4 includes verification that the sponsor is defining CMR correctly. This could lead to a no finding in both places for the same mistake.	MSC-9b, deleted: "Excludes members who were not delivered a CMR per CMS definitions (including a person-to-person, interactive CMR conducted in real-time with a written summary delivered to the member)."	N/A
118	8/10/2012	DV Standards, FDCF	MTM, MSC-10b: change "should be" to "is" to remove any potential confusion or room for interpretation.	MSC-10b, changed: "Properly identifies and includes the number of prescriber interventions within the reporting period for each applicable member, regardless of the success or result of the intervention, and counts these interventions based on the number of unique interventions made to prescribers (e.g., the number is not equal to the total number of prescribers that received intervention recommendations from the organization). Organization does not count each individual problem identified per prescriber intervention (e.g., if the organization sent a prescriber a fax identifying 3 drug therapy problems for a member, this should be reported as 1 intervention)." TO:	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
				<p>"Properly identifies and includes the number of prescriber interventions within the reporting period for each applicable member, regardless of the success or result of the intervention, and counts these interventions based on the number of unique interventions made to prescribers (e.g., the number is not equal to the total number of prescribers that received intervention recommendations from the organization). Organization does not count each individual problem identified per prescriber intervention (e.g., if the organization sent a prescriber a fax identifying 3 drug therapy problems for a member, this is reported as 1 intervention)."</p>	
119	8/10/2012	DV Standards, FDCF	<p>Grievances (Part D): Add guidance to reflect updated policy clarification on aggregating quarterly data before applying 90% threshold.</p>	<p>Added the following two statements to the header information for Part D Grievances:</p> <p>"Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold."</p> <p>"Note to reviewer: Apply the 90% threshold to the total count of grievances calculated. Do not apply the 90% threshold to individual grievance categories."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
120	8/10/2012	DV Standards, FDCF	Grievances (Part D), DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A
121	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions: Add guidance to reflect updated policy clarification on aggregating quarterly data before applying 90% threshold.	<p>Added the following statement to the header information for Coverage Determinations and Exceptions:</p> <p>"Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
122	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A
123	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-3b: Update to reflect clarified guidance to standards in Procedure Manual re: "other outputs."	<p>MSC-3b, changed:</p> <p>"All source, intermediate, and final stage data sets relied upon to enter data into HPMS are archived."</p> <p>TO:</p> <p>"All source, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived."</p>	N/A
124	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-6: Update per the new language in the Part D Technical Specifications: "Multiple transactions for the same claim should be counted individually." This is in response to Question #64 in the Part D Industry Questions spreadsheet.	<p>Added MSC-6d:</p> <p>"If a prescription drug claim contains multiple rejections, each rejection is calculated as a separate pharmacy transaction."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
125	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-7a: Update to reflect language in the Part D Technical Specifications re: "date of decision."	<p>MSC-7a, changed:</p> <p>"Includes all coverage determinations/exceptions with a date of receipt that occurs during the reporting period, regardless of when the final decision was made."</p> <p>TO:</p> <p>"Includes all coverage determinations/exceptions with a date of decision that occurs during the reporting period, regardless of when the request for coverage determination or exception was received."</p>	N/A
126	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-8a: Remove as this is repetitive of MSC-7a.	<p>MSC-8a, deleted:</p> <p>"Includes all PA decisions made (both favorable and unfavorable) with a date of decision that occurs during the reporting period."</p>	N/A
127	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-9d: change "should be" to "is" to remove any potential confusion or room for interpretation.	<p>MSC-9d, changed:</p> <p>"Number calculated for timely PA decisions (Data Element D) should be a subset of the number of PA decisions made (Data Element C)."</p> <p>TO:</p> <p>"Number calculated for timely PA decisions (Data Element D) is a subset of the number of PA decisions made (Data Element C)."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
128	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-10: Add language to exclude IRE decisions from the count for Data Element E in response to Question #70 in the Part D Industry Questions spreadsheet and to align with the updated language in the Part D Technical Specifications that only decisions "made by the plan" are to be included.	Added MSC-10c: "Excludes decisions made by the IRE."	N/A
129	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-10d: change "should be" to "is" to remove any potential confusion or room for interpretation.	MSC-10d, changed: "Number calculated for approved PA decisions (Data Element E) should be a subset of the number of PA decisions made (Data Element C)." TO: "Number calculated for approved PA decisions (Data Element E) is a subset of the number of PA decisions made (Data Element C)."	N/A
130	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-11a: Remove as this is repetitive of MSC-7a.	MSC-11a, deleted: "Includes all decisions made on UM Exceptions (both favorable and unfavorable) with a date of decision that occurs during the reporting period."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
131	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-12: add guidance based on Chapter 18, Sections 40, 50 and 130 of the Prescription Drug Benefit Manual re: notification to the prescribing physician or other prescriber of the decision.	<p>MSC-12a, changed:</p> <p>"Includes only exception decisions for which the member is notified of the decision according to the following timelines:</p> <p>For directly exceptions: For directly exceptions: as the enrollee's health condition requires, but no later than 72 hours after receipt of the request.</p> <p>For indirectly exceptions: For indirectly exceptions: as the enrollee's health condition requires, but no later than 24 hours after receipt of the request."</p> <p>TO:</p> <p>"Includes only exception decisions for which the member (and the prescribing physician or other prescriber involved, as appropriate) is notified of the decision according to the following timelines:</p> <p>For directly exceptions: For directly exceptions: as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement.</p> <p>For indirectly exceptions: For indirectly exceptions: as the enrollee's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
132	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-12: add guidance based on Chapter 18, Sections 40, 50 and 130 of the Prescription Drug Benefit Manual re: notification to the prescribing physician or other prescriber of the decision.	<p>MSC-12b, changed:</p> <p>"Excludes favorable determinations in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:</p> <p>For conditionally exceptions, the sponsor's health condition requires, but no later than 72 hours after receipt of the request.</p> <p>For expedited exceptions, the sponsor's health condition requires, but no later than 24 hours after receipt of the request."</p> <p>TO:</p> <p>"Excludes favorable exception decisions determinations in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:</p> <p>For conditionally exceptions, the sponsor's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement."</p> <p>For expedited exceptions, the sponsor's health condition requires, but no later than 24 hours after receipt of the physician's or other prescriber's supporting statement."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
133	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-12d: change “should be” to “is” to remove any potential confusion or room for interpretation.	<p>MSC-12d, changed:</p> <p>"Number calculated for timely exception decisions (Data Element G) should be a subset of the number of exception decisions made (Data Element F)."</p> <p>TO:</p> <p>"Number calculated for timely exception decisions (Data Element G) is a subset of the number of exception decisions made (Data Element F)."</p>	N/A
134	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-13: Add language to exclude IRE decisions from the count for Data Element H in response to Question #70 in the Part D Industry Questions spreadsheet and to align with the updated language in the Part D Technical Specifications that only decisions "made by the plan" are to be included.	<p>Added MSC-13c:</p> <p>"Excludes decisions made by the IRE."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
135	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-13d: change “should be” to “is” to remove any potential confusion or room for interpretation.	<p>MSC-13d, changed:</p> <p>"Number calculated for favorable UM exception decisions (Data Element H) should be a subset of the number of UM exception decisions made (Data Element F)."</p> <p>TO:</p> <p>"Number calculated for favorable UM exception decisions (Data Element H) is a subset of the number of UM exception decisions made (Data Element F)."</p>	N/A
136	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-14a: Update to reflect language in the Part D Technical Specifications re: "date of decision."	<p>MSC-14a, changed:</p> <p>"Includes all decisions (both favorable and unfavorable) on whether to permit a member to obtain a non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier, with a date of decision that occurs during the reporting period."</p> <p>TO:</p> <p>"Includes all decisions (both favorable and unfavorable) on whether to permit a member to obtain a non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
137	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-16: Add language to exclude IRE decisions from the count for Data Element K in response to Question #70 in the Part D Industry Questions spreadsheet and to align with the updated language in the Part D Technical Specifications that only decisions "made by the plan" are to be included.	Added MSC-16c: "Excludes decisions made by the IRE."	N/A
138	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-11a: Update to reflect language in the Part D Technical Specifications re: "date of decision."	MSC-17a, changed: "Includes all decisions (both favorable and unfavorable) on whether to permit a member to obtain a Part D drug that is not included on the formulary, with a date of decision that occurs during the reporting period." TO: "Includes all decisions (both favorable and unfavorable) on whether to permit a member to obtain a Part D drug that is not included on the formulary."	N/A
139	8/10/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-19: Add language to exclude IRE decisions from the count for Data Element N in response to Question #70 in the Part D Industry Questions spreadsheet and to align with the updated language in the Part D Technical Specifications that only decisions "made by the plan" are to be included.	Added MSC-19c: "Excludes decisions made by the IRE."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
140	8/10/2012	DV Standards, FDCF	Redeterminations: Add guidance to reflect updated policy clarification on aggregating quarterly data before applying 90% threshold.	<p>Added the following statement to the header information for Redeterminations:</p> <p>"Note to reviewer: Aggregate all quarterly data submitted within the reporting year before applying the 90% threshold."</p>	N/A
141	8/10/2012	DV Standards, FDCF	Redeterminations, DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
142	8/10/2012	DV Standards, FDCF	Redeterminations, MSC-4: return the original reference to Subpart M (instead of B). Subpart B is the section about eligibility and enrollment.	<p>MSC-4, changed:</p> <p>"Organization properly defines the term "Redetermination" in accordance with Title 2, Part 423, Subpart B §423.560, §423.580, §423.582, §423.584, and §423.590 and the Prescription Drug Benefit Manual Chapter 18, Section 70, and 130. This includes applying all relevant guidance properly when performing its calculations and categorizations."</p> <p>TO:</p> <p>"Organization properly defines the term "Redetermination" in accordance with Title 2, Part 423, Subpart M §423.560, §423.580, §423.582, §423.584, and §423.590 and the Prescription Drug Benefit Manual Chapter 18, Section 70, and 130. This includes applying all relevant guidance properly when performing its calculations and categorizations."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
143	8/10/2012	DV Standards, FDCF	Redeterminations, MSC-5b: delete “made” and “time” to align with the language in Part D Technical Specifications.	<p>MSC-5b, changed:</p> <p>"Includes all redeterminations decisions for Part D drugs made with a date of final decision that occurs during the reporting time period, regardless of when the request for redetermination was received or when the member was notified of the decision."</p> <p>TO:</p> <p>"Includes all redeterminations decisions for Part D drugs with a date of final decision that occurs during the reporting period, regardless of when the request for redetermination was received or when the member was notified of the decision."</p>	N/A
144	8/10/2012	DV Standards, FDCF	Redeterminations, MSC-7: Add language to exclude IRE decisions from the count for Data Elements C and D in response to Question #56 in the Part D Industry Questions spreadsheet and to align with the updated language in the Part D Technical Specifications that only decisions "made by the plan" are to be included.	<p>Added MSC-7c:</p> <p>"Excludes decisions made by the IRE."</p>	N/A
145	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization: Add guidance in response to #98 in the Part D Industry Questions spreadsheet and to align with the note in the updated Part D Technical Specifications, which states: "Contracts with both 800-series plans and individual plans report only data for individual plans."	<p>Added the following statement to the header information for Long-Term Care Utilization:</p> <p>"Note to reviewer: For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
146	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization, DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	<p>DV Standard 1a, changed:</p> <p>"Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
147	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization, MSC-6d: update in response to question #101 in the Part D Industry Questions spreadsheet and to align with the revision made in Allowable Values for Element C: "Claims with patient residence code 03 may be used to identify enrollees. The LTI report may be another tool for this reporting." The note re: location codes 04 and 07 has been removed.	<p>MSC-6d, changed:</p> <p>"Includes only members who resided in a long-term care facility on the date of service for that Part D drug at the time the Part D claim for that member was processed. Note to reviewer: Claims with location code 03 or the LTI report may be used to identify applicable members. Claims with location code 04 or 07 should not be included."</p> <p>TO:</p> <p>"Includes only members who resided in a long-term care facility on the date of service for that Part D drug at the time the Part D claim for that member was processed. Note to reviewer: Claims with patient residence code 03 or the LTI report may be used to identify applicable members."</p>	N/A
148	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization, MSC-7: add language in response to question #108 in the Part D Industry Questions spreadsheet, as Element D should only include the information for pharmacies in Element A.	<p>Added MSC-7e:</p> <p>"Number calculated for Data Element D is a subset of the total number of network LTC pharmacies calculated for Data Element A."</p>	N/A
149	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization, MSC-8: add language in response to question #108 in the Part D Industry Questions spreadsheet, as Element D should only include the information for pharmacies in Element A.	<p>Added MSC-8f:</p> <p>"Number calculated for Data Element D is a subset of the total number of network LTC pharmacies calculated for Data Element A."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
150	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization, MSC-9: add language in response to question #108 in the Part D Industry Questions spreadsheet, as Element D should only include the information for pharmacies in Element A.	Added MSC-9g: "Number calculated for Data Element D is a subset of the total number of network LTC pharmacies calculated for Data Element A."	N/A
151	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization, MSC-10: add language in response to question #108 in the Part D Industry Questions spreadsheet, as Element E should only include the information for pharmacies in Element B.	Added MSC-10f: "Number calculated for Data Element E is a subset of the total number of network retail pharmacies calculated for Data Element B."	N/A
152	8/10/2012	DV Standards, FDCF	Long-Term Care Utilization, MSC-11: add language in response to question #108 in the Part D Industry Questions spreadsheet, as Element E should only include the information for pharmacies in Element B.	Added MSC-11g: "Number calculated for Data Element E is a subset of the total number of network retail pharmacies calculated for Data Element B."	N/A
153	8/10/2012	DV Standards, FDCF	Plan Oversight of Agents (Part D), DV Standard 1a: Remove the words "and output" to reflect clarified guidance to standards in Procedure Manual.	DV Standard 1a, changed: "Source documents and output are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS." TO: "Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
154	8/10/2012	DV Standards, FDCF	Plan Oversight of Agents (Part D), MSC-5a: update in response to #183 in the Part C Industry Questions spreadsheet.	<p>MSC-5a, changed:</p> <p>"Includes all agents with investigations that were completed during the applicable reporting period, regardless of when the complaint was received."</p> <p>TO:</p> <p>"Includes all agents with investigations that were completed during the applicable reporting period, regardless of when the complaint was received and whether the member remained enrolled, disenrolled, or declined enrollment during the enrollment process."</p>	N/A
155	8/10/2012	DV Standards, FDCF	Plan Oversight of Agents (Part C), MSC-5: update in response to #183 in the Part C Industry Questions spreadsheet.	<p>Added MSC-5d:</p> <p>"Excludes investigations in which the member or agent could be not contacted."</p>	N/A
156	8/10/2012	DV Standards (Acronym Appendix)	Add acronyms for: Comprehensive Medication Review, Current Procedural Terminology, Deep Vein Thrombosis, International Classification of Diseases, 9th Revision, Present on Admission, and Targeted Medication Review.	<p>DV Standards Appendix, added:</p> <p>"CMR - Comprehensive Medication Review CPT - Current Procedural Terminology DVT - Deep Vein Thrombosis ICD 9 - International Classification of Diseases, 9th Revision POA - Present on Admission TMR - Targeted Medication Review"</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
157	8/10/2012	DV Standards (Acronym Appendix)	Remove the acronym for Primary Care Physician.	DV Standards Appendix, deleted: "PCP - Primary Care Physician"	N/A
158	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-8: Add measure-specific criteria to including similar "definition verification" language for consistency with MSC-14a and 17a.	Added MSC-8a: "Includes all decisions made (both favorable and unfavorable) on whether a member has, or has not, satisfied a PA requirement."	N/A
159	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-9: eliminate reference to "sponsor."	MSC-9, changed: "Organization accurately calculates the number of PA decisions for which the Part D sponsor provided a timely notification of the decision, including the following criteria:" TO: Organization accurately calculates the number of PA decisions for which it provided a timely notification of the decision, including the following criteria:"	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
160	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-9b: eliminate reference to “sponsor.”	<p>MSC-9b, changed:</p> <p>"Excludes favorable determinations in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p> <p>TO:</p> <p>"Excludes favorable determinations in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p>	N/A
161	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-11: Add measure-specific criteria to including similar “definition verification” language for consistency with MSC-14a and 17a.	<p>Added MSC-11a:</p> <p>"Includes all decisions made (both favorable and unfavorable) where a member/prescribing physician is seeking an exception to a PA or other UM requirement (e.g., a physician indicates that the member would suffer adverse effects if he or she were required to satisfy the PA requirement)."</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
162	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-12: eliminate reference to “sponsor.”	<p>MSC-9, changed:</p> <p>"Organization accurately calculates the number of UM exception decisions for which the Part D sponsor provided a timely notification of the decision, including the following criteria:"</p> <p>TO:</p> <p>Organization accurately calculates the number of UM exception decisions for which it provided a timely notification of the decision, including the following criteria:"</p>	N/A
163	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-12b: eliminate reference to “sponsor.”	<p>MSC-9b, changed:</p> <p>"Excludes favorable exception decisions in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p> <p>TO:</p> <p>"Excludes favorable exception decisions in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
164	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-15: eliminate reference to “sponsor.”	<p>MSC-15, changed:</p> <p>"Organization accurately calculates the number of tier exception decisions for which the Part D sponsor provided a timely notification of the decision, including the following criteria:"</p> <p>TO:</p> <p>Organization accurately calculates the number of tier exception decisions for which it provided a timely notification of the decision, including the following criteria:"</p>	N/A
165	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-15b: eliminate reference to “sponsor.”	<p>MSC-15b, changed:</p> <p>"Excludes favorable exception decisions in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p> <p>TO:</p> <p>"Excludes favorable exception decisions in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
166	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-16: remove the redundancy with “favorable” and “approved” in the same sentence.	<p>MSC-16, changed:</p> <p>"Organization accurately calculates the number of favorable tier exception decisions made that were approved, including the following criteria:"</p> <p>TO:</p> <p>"Organization accurately calculates the number of tier exception decisions made that were approved, including the following criteria:"</p>	N/A
167	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-18a: correct the typo (the word "is" appears twice, adjacent to each other).	<p>MSC-18a, changed:</p> <p>"Includes only exception decisions for which the member (and the prescribing physician or other prescriber involved, as appropriate) is notified of the decision according to the following timelines:"</p> <p>TO:</p> <p>"Includes only exception decisions for which the member (and the prescribing physician or other prescriber involved, as appropriate) is notified of the decision according to the following timelines:"</p>	N/A

Comment ID #	Date Received	DV Document	Comment	CMS Response	Burden Impact
168	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-18: eliminate reference to “sponsor.”	<p>MSC-18, changed:</p> <p>"Organization accurately calculates the number of formulary exception decisions for which the Part D sponsor provided a timely notification of the decision, including the following criteria:"</p> <p>TO:</p> <p>Organization accurately calculates the number of formulary exception decisions for which it provided a timely notification of the decision, including the following criteria:"</p>	N/A
169	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-18b: eliminate reference to “sponsor.”	<p>MSC-18b, changed:</p> <p>"Excludes favorable exception decisions in which the sponsor did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p> <p>TO:</p> <p>"Excludes favorable exception decisions in which the organization did not authorize or provide the benefit or payment under dispute according to the following timelines:"</p>	N/A

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170	9/24/2012	DV Standards, FDCF	Coverage Determinations and Exceptions, MSC-19: remove the redundancy with “favorable” and “approved” in the same sentence.	MSC-19, changed: "Organization accurately calculates the number of favorable formulary exception decisions made that were approved, including the following criteria:" TO: "Organization accurately calculates the number of formulary exception decisions made that were approved, including the following criteria:"	N/A
171	10/5/2012	FDCF	MSC-5 should be mapped to Data Element 13.2; currently no data element is designated.	MSC-5 in the FDCF, added: "Data Element 13.2"	N/A
172	10/5/2012	FDCF	MSC-16c should be mapped to Data Element K; currently no data element is designated.	MSC-16c in the FDCF, added: "Data Element K"	N/A
173	10/5/2012	FDCF	MSC-18c should be mapped to Data Element K; currently no data element is designated.	MSC-18c in the FDCF, added: "Data Element M"	N/A
174	10/5/2012	FDCF	MSC-5c should be mapped to Data Element A; currently no data element is designated.	MSC-5c in the FDCF, added: "Data Element A"	N/A
175	10/5/2012	FDCF	MSC-5f should be mapped to Data Element A; currently no data element is designated.	MSC-5f in the FDCF, added: "Data Element A"	N/A

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176	8/30/2012	OAI	OAI will be mandatory for sponsoring organizations to complete.	<p>Changed statement: "While not mandatory, it is strongly recommended that organizations complete the OAI to add efficiencies to the review process." to "CMS requires that organizations complete the OAI to add efficiencies to the review process." Deleted statement: "If an organization does not elect to complete the OAI, the reviewer will use the same tool to collect this information during the site visit review, extending the length of the review."</p> <p>Changed any instances of "should" to "must" relating to completion of the OAI.</p>	N/A

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177	9/18/2012	OAI	Sponsoring Organizations must begin completion of the OAI prior to the start of the data validation review period but cannot send the OAI and related materials to the Data Validation Contractor prior to the start of the April 1 review period.	<p>Changed statement: "In the early stage of the data validation review process, and prior to the site visit, the reviewer should request that the organization begin completion of the OAI." to "Prior to the start of the data validation review period, the organization must begin completion of the OAI."</p> <p>Changed statement: "Organizations electing to complete the OAI should complete each section in advance of the site visit, or according to the set timeline of the reviewer" to "Organizations must complete each section of the OAI in advance of the data validation review period, or according to the set timeline of the reviewer. The organization should complete the OAI and provide documentation to the reviewer as early as possible at the start of the data validation review period so that the DVC can begin recalculations on April 1."</p> <p>Inserted table titled Timeline of OAI Activities in the Instructions section.</p>	N/A

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178	10/11/2012	Appendix B	Appendix B: MTM overview: specify that MTM data is uploaded through Gentran and not the HPMS submission tool.	<p>MTM overview, changed:</p> <p>“Data file created for submission to CMS and copy of HPMS screen shots of data entered”</p> <p>TO:</p> <p>“Data file created for submission to CMS”</p>	N/A
179	10/11/2012	Appendix B, FDCF	MTM, MSC-5: specify that MTM data is uploaded through Gentran and not the HPMS submission tool.	<p>MSC-5, changed:</p> <p>“Organization accurately identifies data on MTM program participation and uploads it into the HPMS submission tool, including the following criteria:”</p> <p>TO:</p> <p>“Organization accurately identifies data on MTM program participation and uploads it into Gentran, including the following criteria:”</p>	N/A

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180	10/11/2012	Appendix B, FDCF	MTM, MSC-6: specify that MTM data is uploaded through Gentran and not the HPMS submission tool.	<p>MSC-6, changed:</p> <p>“Organization accurately identifies MTM eligible long-term care facility residents and uploads it into the HPMS submission tool, including the following criteria:”</p> <p>TO:</p> <p>“Organization accurately identifies MTM eligible long-term care facility residents and uploads it into Gentran, including the following criteria:”</p>	N/A
181	10/11/2012	Appendix B, FDCF	MTM, MSC-7: specify that MTM data is uploaded through Gentran and not the HPMS submission tool.	<p>MSC-7, changed:</p> <p>“Organization accurately identifies data on members who opted-out of enrollment in the MTM program and uploads it into the HPMS submission tool, including the following criteria:”</p> <p>TO:</p> <p>“Organization accurately identifies data on members who opted-out of enrollment in the MTM program and uploads it into Gentran, including the following criteria:”</p>	N/A

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182	10/11/2012	Appendix B, FDCF	MTM, MSC-8: specify that MTM data is uploaded through Gentran and not the HPMS submission tool.	<p>MSC-8, changed:</p> <p>“Organization accurately identifies data on CMR offers and uploads it into the HPMS submission tool, including the following criteria:”</p> <p>TO:</p> <p>“Organization accurately identifies data on CMR offers and uploads it into Gentran, including the following criteria:”</p>	N/A
183	10/11/2012	Appendix B, FDCF	MTM, MSC-9: specify that MTM data is uploaded through Gentran and not the HPMS submission tool.	<p>MSC-9, changed:</p> <p>"Organization accurately identifies data on CMR dates uploads it into the HPMS submission tool, including the following criteria:"</p> <p>TO:</p> <p>"Organization accurately identifies data on CMR dates uploads it into Gentran, including the following criteria:"</p>	N/A

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184	10/11/2012	Appendix B, FDCF	MTM, MSC-10: specify that MTM data is uploaded through Gentran and not the HPMS submission tool.	<p>MSC-10, changed:</p> <p>"Organization accurately identifies data on MTM program interventions and uploads it into the HPMS submission tool, including the following criteria:"</p> <p>TO:</p> <p>"Organization accurately identifies data on MTM program interventions and uploads it into Gentran, including the following criteria:"</p>	N/A
185	10/11/2012	Appendix B, FDCF	Standard 1a, change "HPMS" to "CMS systems: as data is uploaded through different systems for different measures (e.g., MTM data is uploaded through Gentran and not HPMS).	<p>Standard 1a, changed (throughout all measures):</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via HPMS."</p> <p>TO:</p> <p>"Source documents are properly secured so that source documents can be retrieved at any time to validate the information submitted to CMS via CMS systems."</p>	N/A

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186	10/11/2012	Appendix B, FDCF	Standard 3a, change "HPMS" to "CMS systems: as data is uploaded through different systems for different measures (e.g., MTM data is uploaded through Gentran and not HPMS).	<p>Standard 3a, changed (throughout all measures):</p> <p>"Data elements are accurately entered / uploaded into the HPMS tool and entries match corresponding source documents."</p> <p>TO:</p> <p>"Data elements are accurately entered / uploaded into CMS systems and entries match corresponding source documents."</p>	N/A
187	10/11/2012	Appendix B, FDCF	Standard 3b, change "HPMS" to "CMS systems: as data is uploaded through different systems for different measures (e.g., MTM data is uploaded through Gentran and not HPMS).	<p>Standard 3b, changed (throughout all measures):</p> <p>"All source, intermediate, and final stage data sets and other outputs relied upon to enter data into HPMS are archived."</p> <p>TO:</p> <p>"All source, intermediate, and final stage data sets and other outputs relied upon to enter data into CMS systems are archived."</p>	N/A

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188	9/26/2012	DESI	<p>Exhibit 7 Sampling Units and Minimum Sample Size for "Final Stage List"</p> <p>For reporting year 2012, Data Elements A-J have been removed from the measure. Therefore we are left with the Beneficiaries Eligible file that clients upload into HPMS. In reviewing the 6/25/12 draft version of "Appendix 3: Data Extraction and Sampling Instructions", MTMP is still listed as a measure under 'Exhibit 7 Sampling Units and Minimum Sample Size for "Final Stage List"'. The sampling unit suggested is Member ID, and the sampling size is 205.</p> <p>Since the Beneficiaries Eligible file is already at the member level, we are unsure as to how we can effectively sample it for a final stage census review and against what we would compare the file. We are pretty clear on how we could perform the primary source review, but not the final stage census review. Would you be able to provide direction as what you would consider a 'best practice' when it comes to MTMP final stage census review for the coming year?</p>	MTM has been removed from Exhibit 7.	N/A

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189	10/25/2012	All DV Documents	CMS has replaced the terms “section” and “measure” that previously appeared in the Part C and Part D Reporting Requirement Technical Specifications with the term “reporting section.”	<p>The following statement has been added to all DV documents:</p> <p>The terms “section” and “measure” that previously appeared in the <i>Part C and Part D Reporting Requirement Technical Specifications</i> have been replaced with the term “reporting section.” To ensure alignment with this new terminology, all references in the data validation documents to the term “measure” have been replaced with the term “reporting section.” In addition, the term “measure-specific criteria” has also been revised and replaced with “reporting section criteria.”</p>	N/A