CMS 60-Day Comment Tracking: Includes FDMS Public Comments and Other Lessons Learned

Comment ID	Method of Comment	Organization	FDMS ID	Date Received	DV Document	Comment	CMS Response	Burden Impact
1	FDMS	Booz Allen Hamilton	0001	4/16/2010	N/A	This is a test only.	No response required.	N/A.
2	FDMS	Medical Mutual of Ohio	0003	6/11/2010	Supporting Statement	Section B, #18, of the 508 Supporting Statement says that plans are exempt from data validation if they terminate their contracts prior to the start of the collection year. We are terminating our MA-PD contracts effective 12/31/10. Would the "collection year" in this case be 2011, so that would make us exempt from validating our 2010 data? My email address is debbie.surace@mmoh.com. Thank you.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
3	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	Data Validation Standards	Sec 2- Please clarify what "applicable CMS contract" means. Can data be separated into part C versus part D? or does data need to be separated by Medicare HMO versus POS etc.?	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
4	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	Data Validation Standards	Sec 5c- CMS in the past did not request inpatient files. This element refers to "concurrent" org determinations. Is this referring to inpatient acute or only post acute, home care and physical therapy?	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
5	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	Data Validation Standards	Sec 5i- Need confirmation on what is being requested. Based on language, I interpret it as a home care or physical therapy request for additional visits should be excluded from sample. Please confirm.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
6	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	Data Validation Standards	Validation standards: Is the expectation the contractor will review programming codes? If so, how will you ensure there are uniform criteria since plans utilize different systems?	No change is required; comment is already addressed in document.	N/A.

7	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	Data Validation Standards	Is CMS going to provide a standardized questionnaire for interviewing plan management? How will you ensure the contractor is asking all plans the same questions during the interview process?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
8	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	Data Validation Standards	Validation standards: What criteria are you using to determine if source & output documents are properly secured? Is this from a physical or IT perspective?	Proper security of source and output documents is required from both a physical and IT standpoint. Hardcopy and electronic copies of documents that contain PII or PHI should be secured per any corporate policies and HIPAA requirements.	No change.
9	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	N/A	We would like CMS to provide a list of "certified contractors".	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
10	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	N/A	Are you requiring the contractor to make a site visit to validate data or is a desk review acceptable.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
11	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	N/A	Is there an appeal process? Plans should have the ability to comment within a certain time period after the contractor submits to CMS.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
12	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	N/A	Will plans have the ability to change contractors during the audit?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

13	FDMS	Horizon Blue Cross Blue Shield of New Jersey	0004	6/15/2010	N/A	One of the standards is to identify if the data fields have meaningful, consistent labels. This appears to be very subjective. Can CMS specify what exactly they are looking for.	Data field labels should be descriptive and have supporting documentation that allows the reviewer to ascertain the data field meaning and intended usage.	No change.
14	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Can sponsors use the same vendor for the pre-assessment and the audit?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
15	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Will CMS please clarify the timing of the audit and exactly what CY data will be audited?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
16	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Will the Pass/Fail (i.e. No-Pass) scoring be at the contract level?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
17	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Can a sponsor use the same vendor for both the pre-assessment, including the completion of the OAI and data validation audit without any conflict of interest?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
18	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	In the case of a PBM which has, for example, 20 plans, do they need to have multiple vendors or can they use one vendor to certify the entire process?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

19	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	What documentation will CMS expect to review from sponsors (i.e. such as flow charts, policies & procedures)?	CMS will review the final findings from the DV contractor, but can request working papers or any documents that were reviewed during the review. The DV Contractor will review all documentation that is requested in the OAI and documentation from the site visit and follow-up data requests.	No change.
20	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Would CMS allow sponsors to first validate the Part C reports and then at a later date, validate the Part D reports?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
21	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Would it be feasible for CMS to do the Part C and the Part D Data Validation Requirements on a three year schedule with one third of the reports being done each year considering for larger plans, this may be very expensive and labor intensive?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
22	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	When will the training be for Part C and Part D sponsors related to the DVR audits in 2010?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
23	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Please clarify the cost burden for a Medicare Advantage sponsor to complete the Part C and the Part D DVR for one calendar year.	The burden estimates have been revised. Please see the updated Supporting Statement for the updated assumptions and calculations.	N/A.

24	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Part C and Part D Medicare Advantage sponsors wish to practice due diligence when selecting an outside auditor for the upcoming audit engagement. CMS provided some hourly estimates in the Supporting Statement for Paperwork Reduction Act Submissions; Medicare Part C and Part D Data Validation (42 C.F.R. §422.516(g) and §423.514(g));however, will CMS estimate the cost per hour it believes is reasonable for a sponsor to hire an auditor to complete the Final Part C and Part D DVR guidance? Furthermore, will CMS estimate the cost burden to a MA sponsor by contract (i.e. many sponsors have several contracts with multiple plan benefit packages associated with each contract)? If this estimate is not available by contract, please explain how CMS derived the estimated cost.	The burden estimates have been revised. Please see the updated Supporting Statement for the updated assumptions and calculations.	N/A.
25	FDMS	Blue Cross Blue Shield of TN	0005	6/15/2010	N/A	Will the Part C Benefit Utilization report be audited during the Spring 2011 data validation effort given the data reported at that time will be for 2009?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
26	FDMS	Coventry Health Plan	0006	6/18/2010	N/A	What methodology will CMS use to derive an overall "pass" or "fail" determination?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
27	FDMS	Coventry Health Plan	0006	6/18/2010	N/A	Will it be up to the vendor to assign pass/fail or CMS to make final determination based upon comments/results from vendor?	No change required. The "Findings Data Collection Form Introduction" provides this guidance (the Pass/Not Pass Determination will be performed by CMS).	No change.

28	FDMS	Coventry Health Plan	0006	6/18/2010	N/A	What will result if an element does not pass based upon the sample selected?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
29	FDMS	Coventry Health Plan	0006	6/18/2010	N/A	What rationale was used to determine which elements required to be audited? For example, Employer Group demographic data?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
30	FDMS	Coventry Health Plan	0006	6/18/2010		Would CMS be willing to share lessons learned or results from best practices from validation audits that have been piloted?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
31	FDMS	Coventry Health Plan	0007	6/18/2010		What methodology will CMS use to derive an overall "pass" or "fail" determination?	Duplicate of FDMS 0006.	N/A.
32	FDMS	Coventry Health Plan	0007	6/18/2010		Will it be up to the vendor to assign pass/fail or CMS to make final determination based upon comments/results from vendor?	Duplicate of FDMS 0006.	N/A.
33	FDMS	Coventry Health Plan	0007	6/18/2010		What will result if an element does not pass based upon the sample selected?	Duplicate of FDMS 0006.	N/A.
34	FDMS	Coventry Health Plan	0007	6/18/2010		What rationale was used to determine which elements required to be audited? For example, Employer Group demographic data?	Duplicate of FDMS 0006.	N/A.
35	FDMS	Coventry Health Plan	0007	6/18/2010		Would CMS be willing to share lessons learned or results from best practices from validation audits that have been piloted?	Duplicate of FDMS 0006.	N/A.

36	FDMS	Argus Health Systems	0008	6/18/2010	OAI	Section 2.2 states "All documentation and responses to questions should reflect the organization's systems and processes that were in place during the reporting period(s) undergoing the data validation review." As the processes used to create reports may include tools where source code management is rudimentary, this proposed requirement may introduce additional complexity to an organization's IT infrastructure to: 1. Maintain multiple versions of IT components (code, data dictionary, etc.) 2. Implement a methodology that readily tracks point-in-time changes to IT components 3. Develop a capability to link to those IT changes and access the variations in code. Additionally, as some reports may result from combining data from service providers with data from the Part D sponsor, systems and processes from multiple parties need to be consolidated as a single flow. It would be preferable to make this proposed requirement effective for CY 2012 to provide organizations the time needed to develop and implement the needed capabilities.	No change required (no change in policy).	No change.
37	FDMS	Argus Health Systems	0008	6/18/2010	OAI	Section 2.2 states *"The organization is responsible for ensuring that it has established mutually agreeable methods for sharing proprietary and/or secure (PHI/PII) data with the reviewer and that the reviewer complies with all HIPAA privacy and security requirements."* The Business Associate Agreement is the standard mechanism for establishing HIPAA compliance obligations with parties receiving PHI. For Part D sponsor data this is the responsibility of the Part D organization. We recommend establishment of standard accepted methods for such transmissions and similar to what occurs for sending secured information to CMS, reviewers should be required to prove to CMS that they have such existing capabilities.	It is up to the organization and contractor to work out mutually agreeable and HIPAA compliant methods for sharing proprietary and/or secure data.	No change.

38	FDMS	Argus Health Systems	0008	6/18/2010	OAI	Section 5.1 states *"For the contract(s) included in this version of the OAI, organizations should provide programming code/source code and example output for computer programs used to calculate the data collected for each of the CMS data measures that are currently undergoing data validation review (as identified in Section 3.3)."* Please clarify if a code sample or complete program code is proposed as the requirement. In either approach, since code and all corresponding components (e.g., data dictionary) are proprietary information, a standard provision of providing code must be an obligation with the reviewer that stipulates: 1. The reviewer is responsible for protecting the intellectual property of the providing organization 2. Code will only be used for purposes of the Data Validation efforts 3. The reviewer will indemnify the providing organization if information is otherwise disclosed or used for other purposes	It is up to the organization and contractor to work out mutually agreeable and HIPAA compliant methods for sharing proprietary and/or secure data.	No change.
39	FDMS	Argus Health Systems	0008	6/18/2010	OAI	Same comment as 5.1	It is up to the organization and contractor to work out mutually agreeable and HIPAA compliant methods for sharing proprietary and/or secure data.	No change.
40	FDMS	Argus Health Systems	0008	6/18/2010	OAI	Same comment as 5.1	It is up to the organization and contractor to work out mutually agreeable and HIPAA compliant methods for sharing proprietary and/or secure data.	No change.
41	FDMS	Argus Health Systems	0008	6/18/2010	OAI	Same comment as 5.1	It is up to the organization and contractor to work out mutually agreeable and HIPAA compliant methods for sharing proprietary and/or secure data.	No change.
42	FDMS	Argus Health Systems	0008	6/18/2010	Data Validation Standards	See comments in 2.2	No change required (no change in policy).	No change.
43	FDMS	Argus Health Systems	0008	6/18/2010	Data Validation Standards	See comments in 2.2	No change required (no change in policy).	No change.
44	FDMS	Argus Health Systems	0008	6/18/2010	Data Validation Standards	See comments in 2.2	No change required (no change in policy).	No change.

45	FDMS	Argus Health Systems	0008	6/18/2010	Instructions for Findings Data Collection Form	Any organization providing data should receive the reviewers comments with regard to their findings	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	No change.
46	FDMS	Argus Health Systems	0008	6/18/2010	Findings Data Collection Form	Any organization providing data should receive the reviewers comments with regard to their findings	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	No change.
47	FDMS	Argus Health Systems	0008	6/18/2010	Sampling Instructions	The line item Coverage Determinations/Exceptions has an incorrect Sampling Unit listed (Case ID). The sampling unit should be Claim ID.	No action required (case is not same as claim).	No change.
48	FDMS	Argus Health Systems	0008	6/18/2010	Sampling Instructions	While a CD can be encrypted, it is burdensome to provide information in this manner and expands the risk that organization IP and PHI may be used or disclosed in a manner inconsistent with a BAA or other form of agreement designed to protect such. It is preferable to designate a standard method of exchanging data information that has more robust industry-accepted security. Organizations that do not have this capability should not be accepted as reviewers.	The "Data Extraction and Sampling Instructions" have been updated to allow more flexibility (document now allows for secure storage devices beyond CDs).	No change.
49	FDMS	Health Spring	0009	6/18/2010	Sampling Instructions	What does CMS consider the records to be for the sampling unit? For example, the document entitled Medicare Part C and Part D Measure Sampling Instructions for Data Validation shows the Appeals sample size as 150	No change required.	No change.
50	FDMS	Health Spring	0009	6/18/2010	Sampling Instructions	What "records" are going to be reviewed to validate that the Appeals were processed and classified correctly? How are the auditors going to know if the samples (from the universe of reports numbers) are real appeals and classified counted correctly? The Document Supporting Statement for Paperwork Reduction Act does not address what this documentation will be. All the information just talks about sampling and submitting documentation.	The "Data Extraction and Sampling Instructions" have been updated to add clarification.	No change.

51	FDMS	Health Spring	0009	6/18/2010	Sampling Instructions	Part D realizes there will be other documents that will be supplied; like P&P's, processes and data pull criteria, but we interpret the 150 sample validation to mean extra documentation that would be reviewed and do not see what that documentation is	No change required. Refer to the documentation request provided in the "Organizational Assessment Instrument."	No change.
52	FDMS	Health Spring	0009	6/18/2010	Sampling Instructions	Our current PBM, Argus, also provided comments directly to CMS. Bulletin number # D834	No response required.	N/A.
53	FDMS	Medicare Cost Contractors Alliance	0010	6/18/2010	N/A	Summarization of letter received from Organization: Medicare Cost Plans should not be required to report Part C data or have a Part C data validation requirement	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
54	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	N/A	We encourage CMS to allow PBMs, that provide similar services and reports to multiple Part D plans, to transfer such audit results across plans. To the extent a given Part D plan has a unique aspect to it; we fully support additional Part D plan specific testing and auditing. However, where the parameters and processes are identical, a single sampling across the plans the PBM serves that would satisfy the Data Validation requirements for all plans served by the PBM would greatly improve efficiencies for CMS, plans and PBMs. Upon completion of such an audit, the PBM or CMS could provide the plans with a “audit certification number” for entry into HPMS at a plan level if tracking such information via that repository is required.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
55	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010		The timeline provided indicated that 2010 validation reviews will begin between March and May of 2011. We recommend that this timeframe is moved to the May, through July timeframe because plan sponsors will be handling the First Quarter 2011 reporting during March, April and May, and such a shift would streamline the activity required through the plan year for plans.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

56	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	OAI	The OAI tool needs to be specific to that year's reporting requirements. Please see the following comments regarding the discrepancies noted between the 2010 Data Validation Standards and the 2010 Reporting Requirements. The discrepancies that are noted appear to be requirements that were suspended, removed or changed from prior years reporting requirements and technical specifications and are no longer applicable for 2010.	No change required. The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
57	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Data Validation Standards	This Data Validation Standard measure is different from the approved and distributed Reporting Requirements and Technical Specifications. The 2010 Reporting Requirements, Section VII: Grievances, page 16 : "Multiple grievances by a single complainant should be tracked, followed, and reported as separate grievances." The 2010 Reporting Requirements and the Technical Specifications do not say to combine complaints on the same topic into one grievance. We recommend that the Measure Specific Criteria be updated to reflect the actual 2010 Reporting Requirements and Technical Specifications verbiage.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.

58	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Data Validation Standards	This Data Validation Standard measure is different from the approved and distributed Reporting Requirements and Technical Specifications. The Reporting Requirements document, page 19 states: “A. The total number of pharmacy transactions in the time period above. “ Neither the 2010 Reporting Requirements nor the Technical Specifications state that the transactions were to be included based on a transaction’s date of service for this report. Only the Data Validation Standards say to use date of service. We recommend that the final Data Validation specifications be updated to indicate that the number of pharmacy transactions counted and reported is to be based upon those claims with a processing date that falls within the reporting period. We recommend that the Data Validation Standards match the published 2010 CMS Reporting Requirements and the 2010 Reporting Technical Specifications documents.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
59	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Data Validation Standards	This is not a stated requirement in the 2010 Reporting Requirements or in the Technical Specifications documents. We believe this is a carry over from the 2009 requirements. We recommend that this requirement be removed from the Data Validation requirements.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
60	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Data Validation Standards	This Data Validation Standard measure is different from the approved and distributed Reporting Requirements and Technical Specifications. We recommend that the Data Validation Standards match the published 2010 CMS Reporting Requirements and the 2010 Reporting Technical Specifications documents.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.

61	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Data Validation Standards	This section contains the 2009 Reporting Requirements and needs to be updated to reflect the 2010 Reporting Requirements and Technical Specification information.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
62	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Data Validation Standards	4b. and 5 b. specify to only include pharmacies that were active on the last day of the reporting period. The CMS guidelines do not state on data elements A, B, C, D & E to include only pharmacies that are contracted as of the last day of the reporting period in any of the elements like the data validation reflects. The Technical Specifications under element D (only) does state to report: " Any pharmacy that is active in the network for 1 or more days in reporting period should be included." We recommend that the Data Validation Standards match the published 2010 CMS Reporting Requirements and the 2010 Reporting Technical Specifications documents.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
63	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Sampling Instructions	Please confirm how long does the sponsor or PBM need to retain intermediary data sets (interim and final stage data sets) after the report is generated?	Sponsoring organizations are required to maintain all data to support the reporting requirements for 10 years, per 42 CFR § 422.504(d) and 42 CFR § 423.505(d). All related entities, contractors, or subcontractors must also maintain supporting data for 10 years, per 42 CFR § 422.504(i)(2) and 42 CFR § 423.505(i)(2).	No change.
64	FDMS	SilverScript Insurance Company and Accendo Insurance Company	0011	6/18/2010	Sampling Instructions	In regards to the statement that "one sample must be randomly drawn from pooled data from all contracts". We believe that pooling multiple contracts from a single sponsor will cause a significant burden on the sponsor and on any PBM servicing multiple sponsors that have multiple contracts. The reporting is currently created by contract and the pooling the contracts together for a single sponsor will likely require significant database development if the current design for the reporting databases purposefully keeps the contract data separated.	The "Data Extraction and Sampling Instructions" have been updated to allow pooling as an option. If a reviewer would like to generate random samples of each contract, this is also an option.	No change.

65	FDMS	WellPoint Inc.	0012	6/18/2010	N/A	According to the HPMS memo released on November 23, 2009 (Medicare Part C and D Reporting Requirements and Data Validation), CMS indicates that the CY 2010 data validation audits will occur during the period of approximately March 2011 through May 2011. Based on the answer to question number 26 contained in the November 23, 2009 HPMS memo, it is our understanding that the data validation review of the Benefit Utilization report due August 31, 2011 will be performed prospectively. Additionally, based on the footnote contained on page 7 of this document, CMS indicates that all data validation reviews, with the exception of Part C Benefit Utilization, will be retrospective; however, there are several Part C reports and one Part D report subject to CY 2010 data validation that are due on or after May 31, 2011 (Procedure Frequency, Serious Reportable Adverse Events, Special Needs Plans Care Management, and Long-Term Care Utilization). Since these reports are due at the end of the projected time that the data validation audits will occur, will CMS also be performing a prospective review of these reports? Any clarification that you can provide is appreciated.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
66	FDMS	Blue Care Network of Michigan	0013	6/18/2010	N/A	Reduce the required amount of information if the health plan is already HEDIS audited as much of the information is duplicative.	Language has been added to the "Data Validation Standards" in the Procedure Frequency Measure (2.2) to add clarification.	N/A.
67	FDMS	Blue Care Network of Michigan	0013	6/18/2010	N/A	Review of Part D tech specs could cause a considerable burden on some delegated entities (i.e., PBMs). Consider allowing the PBMs to have an external auditor review those requirements that are applicable and issue a report to the PBM clients (aka plans) which would be acceptable to CMS. More efficient and definitely cost effective	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
68	FDMS	Blue Care Network of Michigan	0013	6/18/2010	N/A	Tech Specs: Procedure Frequency Clarification should be given to when the exclusions apply for each condition. Additionally clarification is requested for items like Procedure Frequency Sections 2.3 and 2.4 which both contain CPT 35472 suggesting that the two buckets are double counting the same procedures	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.

69	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	N/A	We recommend that CMS allow PBMs that use common systems with identical parameters and processes and provide similar services and reports to multiple Part D plans, that the PBM be able to obtain one data validation audit for each of their systems and processes and report the audit results to each of their Part D plans. We believe that where the parameters and processes are identical, a single audit across the systems and/or the plans the PBM serves should satisfy the Data Validation requirements for all Part D plans served by the PBM. Allowing for this provision would greatly improve efficiencies for CMS, Part D plans and PBMs. Upon completion of such an audit, the PBM could provide the plans with a "audit certification number" to provide to their data validation auditor or for use in HPMS if tracking such information is required We agree, that to the extent that a Part D plan has other data systems or processes that support the CMS reports, that a Part D plan would need obtain specific data validation testing and auditing.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
70	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	General	We recommend that the timeline be moved to May through July 2011 as Part D plans will be handling the First Quarter 2011 reporting and PDE submission from March through May. In addition, because the final criteria for hiring a data validation auditor will not be released until fall 2010, it is going to be very difficult to prepare an RFP and get an auditor retained and have them complete their audit in the March to May timeframe. A shift to a May through July would streamline the activity required throughout the plan year for our plan.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
71	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Sampling Instructions	Please confirm in the final instructions how long the sponsor or PBM needs to retain interim and final stage data sets after the report is generated.	Sponsoring organizations are required to maintain all data to support the reporting requirements for 10 years, per 42 CFR § 422.504(d) and 42 CFR § 423.505(d). All related entities, contractors, or subcontractors must also maintain supporting data for 10 years, per 42 CFR § 422.504(i)(2) and 42 CFR § 423.505(i)(2).	No change.

72	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Sampling Instructions	In regards to the statement that “one sample must be randomly drawn from pooled data from all contracts”: Our reporting is currently created by contract and pooling the contracts together will likely require significant database development because the current design for the reporting databases purposefully keeps the contract data separated. We believe that pooling multiple contracts will create a significant burden on us as a plan sponsor and on our PBM.	The "Data Extraction and Sampling Instructions" have been updated to allow pooling as an option. If a reviewer would like to generate random samples of each contract, this is also an option.	No change.
73	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Data Validation Standards	There appear to be discrepancies between the 2010 Data Validation Standards and the 2010 Reporting Requirements. These appear to be requirements that were suspended, removed or changed from prior reporting requirements and technical specifications and are no longer applicable for 2010. Below you will find the areas that do not correspond with each other:	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
74	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Data Validation Standards	This Data Validation Standard measure is different from the approved and distributed Reporting Requirements and Technical Specifications. The 2010 Reporting Requirements, Section VII: Grievances, page 16 states “Multiple grievances by a single complainant should be tracked, followed, and reported as separate grievances.” The 2010 Reporting Requirements and the Technical Specifications do not say to combine complaints on the same topic into one grievance. We recommend that the Measure Specific Criteria be updated to reflect the actual 2010 Reporting Requirements and Technical Specifications verbiage.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.

75	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Data Validation Standards	This Data Validation Standard measure is different from the approved and distributed Reporting Requirements and Technical Specifications. The Reporting Requirements document, page 19 states: “A. The total number of pharmacy transactions in the time period above. “ Neither the 2010 Reporting Requirements nor the Technical Specifications state that the transactions were to be included based on a transaction’s date of service for this report. Only the Data Validation Standards say to use date of service. We recommend that the final Data Validation specifications be updated to indicate that the number of pharmacy transactions counted and reported is to be based upon those claims with a processing date that falls within the reporting period and that the Data Validation Standards match the published 2010 CMS Reporting Requirements and the 2010 Reporting Technical Specifications documents.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
76	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Data Validation Standards	This Data Validation Standard measure is different from the approved and distributed Reporting Requirements and Technical Specifications. We recommend that the Data Validation Standards match the published 2010 CMS Reporting Requirements and the 2010 Reporting Technical Specifications documents.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
77	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Data Validation Standards	This is not a stated requirement in the 2010 Reporting Requirements or in the Technical Specifications documents. We believe was carried over from the 2009 Reporting Requirements and recommend that this requirement be removed from the Data Validation requirements. We recommend that this requirement be removed from the Data Validation requirements.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.

78	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Data Validation Standards	This section contains the 2009 Reporting Requirements and should be updated to reflect the 2010 Reporting Requirements and Technical Specification information.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
79	FDMS	National Rural Electric Cooperative Association	0014	6/18/2010	Data Validation Standards	Measure 4b. and 5 b. specify to only include pharmacies that were active on the last day of the reporting period. The CMS guidelines do not state on data elements A, B, C, D & E to include only pharmacies that are contracted as of the last day of the reporting period in any of the elements like the data validation reflects. The Technical Specifications under element D (only) does state to report: “Any pharmacy that is active in the network for 1 or more days in reporting period should be included.”. We recommend that the Data Validation Standards match the published 2010 CMS Reporting Requirements and the 2010 Reporting Technical Specifications documents	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions). The organization appears to be commenting on earlier versions than the documents posted for public comment in April 2010.	No change.
80	FDMS	Independent Health	0015	6/18/2010	Supporting Statement	Regarding 'Supporting Statement for Paperwork Reduction Act Submissions: Medicare Part C and Part D Data Validation (42 C.F.R. 422.516(g) and 423.514(g))', Section B, 18. Certification Statement, recommend defining or clarifying "data collection year." Is data collection year the year of the data validation collection or the year that the reporting data was collected? For example, the data collection conducted by the independent external reviewer will take place in Spring 2011 while the initial data itself that was collected and reported is from 2010. This clarification would be helpful for a contract that terminates for 2011 determine whether or not it is required to validate 2010 data.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

81	FDMS	Express Scripts	0016	6/18/2010		Express Scripts appreciates the opportunity to provide comments on CMS' April 6thth, 2010 Regulation on Medicare Part C and Part D Data Validation (42 C.F.R. §422.516(g) and §423.514(g)), as required under 1857(e) and 1860D-12 of the Social Security Act. We recognize that developing data standards that would determine reliability, validity, completeness, and comparability of measures reported by plan sponsors is an important undertaking for CMS. We also realize that preparation for detailed external data audits will be a significant challenge for Part D sponsors and their subcontracted pharmacy benefit managers (PBMs). Express Scripts is one of the largest pharmacy benefit management companies in North America. Headquartered in St. Louis, Express Scripts provides integrated PBM services including network-pharmacy claims management, home delivery services, specialty benefit management, benefit-design consultation, drug-utilization review, formulary management and medical and drug data analysis services to more than 50 million Americans. First and foremost, we appreciate CMS' desire to utilize the experience and intimate knowledge that Part D sponsors and their subcontracted pharmacy benefit managers have in collecting and processing data for CMS reported measures. We agree with CMS' conclusion that validating reported data is a necessary precursor to fulfilling its responsibilities in responding to questions from Congress, oversight agencies, and the public. Hence, we are supportive of CMS' decision to standardize data validation across reported measures and data elements and across plans.	No response required.	N/A.

82	FDMS	Express Scripts	0016	6/18/2010		While we are overall supportive of CMS' guidance, we do offer the following recommendations: Audit Timeframe: In the Supporting Statement for Paperwork Reduction Act Submissions – B. Justification -16.Publication/Tabulation Dates, CMS states that the collection of the Part C and Part D validation data will commence around March 1, 2011 and that the audits are expected to occur each year over a three-month period. Express Scripts Recommendation: First, we would request CMS to confirm if we are right to assume that the audits are expected to be completed before May 31, 2011. If so, we believe that the three months given as the audit timeframe will not be sufficient for PBMs. Many plans outsource their reporting to PBMs, and to schedule and accommodate large numbers of simultaneous on-site audits is a significant administrative burden. Based on past experience, we estimate at least five business days of on-site visits, with probable follow-up later. Hence, we strongly recommend CMS to extend the audit period to at least nine months, and preferably to twelve months. This will help not only in scheduling of the audits, but also will increase audit quality and acceptance of results. In addition, it will also alleviate resource and bottleneck issues on the external auditor side, since we believe there are, at present, a limited number of audit firms that have the qualifications that CMS is looking for.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

83	FDMS	Express Scripts	0016	6/18/2010		Pass/Fail Explanation In the Supporting Statement for Paperwork Reduction Act Submissions – B. Justification-1. Need and Legal Basis, CMS states that reviewer will share their findings with the organization and then submit the completed Findings Data Collection Form to CMS, who will process the measure-level or data element-level findings for each measure's standards to derive an overall "Pass" or "Not Pass" determination. In addition, in the answer to Question 15 of the Q&A section of the November 23, 2009 memorandum titled Medicare Part C and Part D Reporting Requirements and Data Validation, CMS has stated that "a scoring system will be developed and a "pass" or "not pass" will be assigned based on information reported to us by the independent data validation contractor hired by the MAO or Part D sponsor." Express Scripts Recommendation: Part C and D Data Validation Audit is the first of its kind and presents a learning opportunity for both the plans and CMS. Hence, instead of deciding upon an evaluation system in advance, we would recommend that CMS use the findings as a guide toward the selection of an evaluation system that would ultimately best focus and direct plans toward CMS' goals of data validity, reliability and comparability. We would also suggest that, before finalizing it, CMS open the evaluation system it proposes to public comment, which could provide helpful insight about its advantages and disadvantages. However, if CMS has made a firm decision toward a Pass/Fail system, then we would request CMS explain the evaluation criteria and methodology on how the Pass/Fail grade will be given. Transparency of the methodology would help plans prevent incorrect or unnecessary weightings, would reduce objections to the outcome of the audit and give more credibility to the final evaluation.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.

84	FDMS	Express Scripts	0016	6/18/2010		Appeals Process In Question 22 of the Q&A section of the November 23, 2009 memorandum titled Medicare Part C and Part D Reporting Requirements and Data Validation, CMS has stated that the plan will not have the right of appeal. CMS also states that the plan may disagree with the results of the audit, but that process solely involves the plan and the external auditor. CMS states in Question 20 of the same memorandum that sponsors "that are found to be deficient will be requested to develop corrective action plans or could be subject to other enforcement actions". It adds that a Fail grade will be considered non-compliant and may be used to adjust plan performance measurement. Express Scripts Recommendation: We would like to understand the implications of failure to pass the audit more clearly, especially the scope of "other enforcement actions" mentioned in the CMS memo. If a failure on any part or whole of the audit can lead into contractual sanctions including prohibition from bidding or contract termination, then we believe that the plans should be provided with an appeals process. Such a process, by itself and by its sheer availability, would reduce issues that may originate from auditor errors or bias, facilitate acceptance of the results and also help CMS maintain accuracy and impartiality in evaluating plans and informing beneficiaries. Otherwise, the plans have no recourse for significant disagreements. As an example and possible precedent, we would like to point out to the three-stage appeals process for RADV payment error calculations mentioned in the MA Part D Final Rule (CMS-4085-F). While the aforementioned interaction is entirely between CMS and the plan, we believe that CMS can institute in this case an appeals process that would allow reexamination of the audit results by a third party, as well as allow plans to appeal to CMS' cumulative evaluation itself.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

85	FDMS	Express Scripts	0016	6/18/2010		Long-term Care Utilization Reports CMS has stated in Medicare Part C and Part D Measure Instructions for Findings Data Collection Form for Data Validation Contractors that Long-term Care Utilization will be included in the 2011 audit. Express Scripts Recommendation: Long-term Care Utilization report for PY 2010 is due on June 30, 2011. Data Validation Audits, which start in March 1, 2011, may end before this report is submitted. In addition, operational build-out, technical development and QA testing of the report process may continue beyond March 1, 2011, before the report is submitted in June. Hence, while we support the evaluation of Long-term Care Utilization reporting, we would recommend that this portion of the audit be carried out in 2012 for PY 2010 data, when the full year of data and the reports will be available.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
86	FDMS	Express Scripts	0016	6/18/2010	Findings Data Collection Form	Data Sharing Risk CMS has stated in the Supporting Statement for Paperwork Reduction Act Submissions that the Findings Data Form "allows the reviewer to record notes, data sources referenced and findings for different standards and criteria specified for a given measure" to be submitted to CMS. In Question 1 of the Q&A section of the November 23, 2009 memorandum, CMS has also mentioned that "audited data will ensure that health and drug plans are on equal footing for public reporting" and, in the 2010 Call Letter and elsewhere, has confirmed that it "may adjust performance measurements to reflect the plan's non-compliance with CMS audit specifications." Express Scripts Recommendation: We are concerned with possible release of sensitive, detailed information that can be traced to plans or PBMs when CMS makes public the results of the audit. We understand CMS' desire to provide as transparent a Part D program as possible, however, we also believe that the data collected by the auditors may reveal to the auditing team and CMS sensitive information, proprietary business processes	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

87	FDMS	UnitedHealth Group	0017	6/18/2010	General	Issue: It is unclear how CMS will derive the "Pass" or "Not Pass" determination. In addition, there is no indication what the process will be for correcting an initial “Not Pass” determination. Recommendation: We recommend clarifying how CMS will derive an overall "Pass" or "Not Pass" determination. For example, will each standard be rated the same or will there be over/under weighting of certain standards? In addition, please clarify if the "Pass" or "Not Pass" determination will be made at the organization or contract level. We further recommend CMS clarify the process for correcting a "Not Pass" determination.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
88	FDMS	UnitedHealth Group	0017	6/18/2010	General	Annual Validation Issue: It appears that the cost and total time involved in this data validation audit has been underestimated. The estimates appear to be for a small plan with only a handful of contracts and a single set of systems for delivering CMS reports. Given the number of systems that may be used by larger plans to report on the broad scope of the measures, this places a significant burden on the handful of qualified Audit Contractors to review both the plan and its delegated entities systems and appropriate documentation within the 12 week timeframe.	The burden estimates have been revised. Please see the updated Supporting Statement for the updated assumptions and calculations.	N/A.
89	FDMS	UnitedHealth Group	0017	6/18/2010	General	Recommendation: We recommend that a limited set of reports be validated each year, as CMS had initially planned, with a three year overall schedule. For example, 1/3 of reports would be validated year 1, the next 1/3 in year 2 etc. We further recommend that the Appeals/grievances measure be included in the first set of reports to be validated. Measures with the first reporting due in 2011 should be included in the third validation set. In the alternative, we recommend allowing a minimum of six months for the validation, which would allow sufficient time for a thorough, quality validation of plan and delegated entities systems, as well as all appropriate documentation.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

90	FDMS	UnitedHealth Group	0017	6/18/2010	General	CMS intends the Data Validation Audits to begin March 1 and occur over a three month time period; however, this is the period in which plans are preparing bids. Recommendation: We recommend the Data Validation Audit be scheduled in the summer so it does not conflict with Plans' bid development. This will also allow for retrospective data review of the 2010 reports that are not due to CMS until May and August of 2011.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
91	FDMS	UnitedHealth Group	0017	6/18/2010	Findings Data Collection Form	Issue: The Review findings instructions indicate that any inaccuracies result in a "no" finding. However, the sampling instructions indicate that the process is designed to "detect error rates of 15% or more." Recommendation: We recommend clarifying the standard that applies and that auditor(s) have the discretion to determine that negligible errors would not exclude a data element from being met.	Part B of the supporting statement has been updated to clarify the 15% error rate.	N/A.
92	FDMS	UnitedHealth Group	0017	6/18/2010	Findings Data Collection Form	Issue: On both the Benefit Utilization and Employer/Union Sponsored Group Health Plan Sponsors (Part D) forms, Standard 3.a "Data elements are accurately entered into the HPMS tool…" does not apply. These reports are file uploads. Recommendation: We recommend marking Standard 3.a as "N/A" on both forms, similar to the manner that the file upload is marked "N/A" for those that are entered via HPMS.	Standard 3.a has been changed to "N/A" on both the Benefit Utilization and the Employer/Union Sponsored Group Health Plan Sponsors findings data collection forms.	No change.
93	FDMS	UnitedHealth Group	0017	6/18/2010	OAI	Issue: Provided in section 3.1 is a list of contract types that includes CCP, SNP, PFFS and Employer/Union "800 Series," etc. However, these types are not mutually exclusive as a contract may be a CCP or PFFS and have some employer group and non- group Plan Benefit Packages (PBPs) within the contract. Recommendation: Since there is specific reporting for SNPs and Employer/Union plans, we recommend identifying the overall contract type, then indicating under that contract type, if there are SNP or 800 series type plans. To accomplish this, we recommend adding an additional 2 columns to identify underlying plan types (PBPs). "Include SNP?" and "Include Employer/Union "800 Series?" These should then be answered as either Yes or No.	Section 3.1 of "Organizational Assessment Instrument" has been revised to accommodate for required plan detail.	No change.

94	FDMS	MCS Advantage, Inc.	0018	6/18/2010	OAI	According to this section the information gathered by the data validation reviewers will provide a better understanding of the scope for the organization's data validation review, including which contract(s) will be reviewed. 1.Which criteria will be considering to select the contract that will be reviewed? It is possible that CMS provide to the MAO's this information?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
95	FDMS	MCS Advantage, Inc.	0018	6/18/2010	Supporting Statement	Who will be responsible for the payment of these services?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	No change.
96	FDMS	MCS Advantage, Inc.	0018	6/18/2010	Supporting Statement	Will CMS recommend any contractors to perform this data validation?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
97	FDMS	MCS Advantage, Inc.	0018	6/18/2010	Supporting Statement	If the MAOs complete the OAI internally, do results have to be submitted to CMS?	No action required. Already in the "Organizational Assessment Instrument" (see instructions).	No change.
98	FDMS	MCS Advantage, Inc.	0018	6/18/2010	Supporting Statement	The result of the data validation will be processed by CMS to determine if those findings "Pass" or "Not Pass", will this document be a formal finding to the MAO?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
99	FDMS	MCS Advantage, Inc.	0018	6/18/2010	Supporting Statement	The independent yearly audit proposed, will be performed by CMS or by auditors hired by the MAO?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

100	FDMS	Kaiser Permanente	0019	6/18/2010		In Section A. ("Background"), CMS states that it will provide "a set of standards for selecting a data validation organization", and these standards will "describe the minimum qualifications, credentials, and resources that the selected data validation contractor must possess." But CMS does not say when it will do this. If CMS intends to make any significant changes to the draft standards it issued in September, 2009, it should do so very quickly. MAOs and Part D sponsors (including Medicare Cost contractors) are even now trying to assess the qualifications of, and select, data validation auditors. If that assessment and selection process must accommodate different qualifications for the auditors, these organizations/sponsors need to know that as soon as possible	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
101	FDMS	Kaiser Permanente	0019	6/18/2010		In Section B, Subsection 16 ("Publication/Tabulation Dates"), CMS states that "Collection of the Part C and Part D validation data will commence on March 1, 2011. The data validation audits are expected to occur each year over a three year period." From this statement, we infer that CMS intends to require that all MAOs and Part D sponsors undergo a data validation audit every year, during the same 3 month period each year. If this is a correct inference, we urge CMS to reconsider. These audits are intensely labor- and resource-intensive, and the number of qualified data validation auditors too small, to accommodate these data validation audits for every organization/sponsor in the country at the same time every year. Kaiser strongly believes that CMS should conduct these data validation audits on a 3 year cycle, as it currently does with the OFM financial solvency audits, so that one-third of MAOs/sponsors undergo data validation audits each year	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

102	FDMS	Kaiser Permanente	0019	6/18/2010	Supporting Statement	There is another concern about the proposed March 1, 2011 "start date". CMS does not explain (and should) how a data validation audit that begins on or around March 1, 2011 could validate measures for which 2010 data is not reported until the end of May, 2011 (Procedure Frequency and Serious Reportable Adverse Events) or until the end of August, 2011 (Benefit Utilization). Kaiser recommends that CMS withdraw these measures from data validation audits conducted during 2011, and reinstate them for audits conducted in 2012.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
103	FDMS	Kaiser Permanente	0019	6/18/2010	OAI	CMS does not state whether this completed tool, which it encourages MAOs/sponsors to complete and give to the data validation auditor before the actual audit, must be given to CMS by either the auditor or the MAO/sponsor. CMS should revise Section 2.1 to clarify that neither the MAO/sponsor nor the auditor will be required to give this completed tool to CMS. Such a clarification will also make moot the issue of whether the completed tool, replete with confidential and proprietary information about an MAO/sponsor's data systems and IT networks, could be the subject of a FOIA request, were it to come into CMS' possession.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

104	FDMS	Kaiser Permanente	0019	6/18/2010	Findings Data Collection Form	In Section 1.1, CMS states that the data validation auditor will use the Findings Data Collection Form to record its audit findings, and "will share these findings with the organization, and then submit the completed... Form to CMS, who will process the measure- or data element-level findings for each measure's standards to derive an overall "Pass" or "Not Pass" determination." It is not clear from this statement whether the audited organization/sponsor has the right to respond formally to its auditor's findings, and the right to have that formal response submitted with the completed Form to CMS. As with other CMS audits, Kaiser strongly believes that audited organizations/sponsors should have the opportunity to hear preliminary findings in an exit conference and respond to those findings with the auditor, so that any confusion or misunderstandings can be resolved before the auditor's final report is issued.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
105	FDMS	Kaiser Permanente	0019	6/18/2010	Findings Data Collection Form	Organizations/sponsors should also be able to have their response to the auditor's report (the completed Form) included when the auditor sends that Form to CMS.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

106	FDMS	Kaiser Permanente	0019	6/18/2010	Findings Data Collection Form	CMS states that it will "process" the auditor's findings to "derive an overall "Pass" or "Not Pass" determination, but CMS does not at all explain or describe how it will do this "processing" or how it will make this crucial "overall determination" of "Pass" or "Not Pass". We don't know how CMS will weight the auditor's findings to determine "Pass" or "Not Pass". For example, if the auditor's findings indicate that the organization/sponsor's data was satisfactorily validated with respect to 15 measures, but not for 2 other measures, would CMS' processing determine that this resulted in a "Pass" or "Not Pass" outcome? Based on what CMS has issued to date, this very important "processing", which will result in the crucial "Pass" or "Not Pass" determination, is a "black box". As such, it is capable of producing arbitrary and capricious results that can do significant damage to an organization/sponsor. Organizations/sponsored are entitled to have a much more robust explanation of CMS' intended "processing" and how it will make "Pass" and "Not Pass" determinations.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
107	FDMS	Kaiser Permanente	0019	6/18/2010	Findings Data Collection Form	There are several elements under Section 2.1.1 ("Benefit Utilization") that ask for "total cost sharing paid by members directly to providers" for various services. (See elements 1.56, 1.64, 1.72, 1.80, 1.88, 1.96, 1.102, 1.108, 1.114, 1.120, 1.126, and 1.130). It is understandable that CMS would want to measure the cost sharing that members pay for various services, but the phrase "paid...directly to providers" is not appropriate for many MAOs. The phrase is actually misleading for Kaiser members, because the cost sharing they pay for these services is not paid "directly to providers". Instead, their cost-sharing is paid to Kaiser, the MAO or Medicare Cost contractor. Kaiser's contracted Permanente physicians do not collect or retain cost-sharing that members pay for covered MA plan services. Kaiser recommends that CMS carefully re-examine what data it is trying to collect in these elements and modify the language of these elements accordingly.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.

108	FDMS	Kaiser Permanente	0019	6/18/2010	Findings Data Collection Form	In Section 2.2.2 ("Medication Therapy Management Programs"), the word "was" should be deleted in Element A. The last sentence, referring to a "currency field", in Element F should be deleted. The inclusion of beneficiary-specific data fields at the end of this Section is puzzling, because the Supporting Statement (at page 10) states that "CMS will not be requesting any beneficiary identification information."	The Findings Data Collection Form instructions have been updated to correct this error. The beneficiary-specific data fields are listed in the instructions for the Findings Data Collection Form because this document lists all data elements that are requested as part of the Part D Reporting Requirements for the MTMP Data Measure, and therefore not covered by the sentence on p 10 of the Supporting Statement. The data collected on the FDCF does not include beneficiary identification information.	No change.
109	FDMS	Kaiser Permanente	0019	6/18/2010	Findings Data Collection Form	In Section 2.2.6 ("Long Term Care Utilization"), Element E requires certain data "In aggregate, for all retail pharmacies in the service area". CMS can not reasonably request data about all retail pharmacies in the service area, because there is no way a Part D sponsor would have that information. Surely CMS means "all network retail pharmacies in the service area" or "all owned and operated retail pharmacies in the service area." CMS should correct this reference.	No response required.	N/A.
110	FDMS	Kaiser Permanente	0019	6/18/2010	Sampling Instructions	Table 1 in Section 1.0 ("Overview") indicates that no sampling is required for the two Employer Group Sponsors measures and the Retail, Home Infusion and LTC Pharmacy Access measure. This is repeated in Table 2 on page 4. However the last sentence of the first paragraph in Section 3.2 ("Evaluating the Sample Data") states that "The validation of all criteria except for meeting deadlines will be conducted using sample data." It is not clear whether this last sentence contradicts the "no sampling" notations in Tables 1 and 2. CMS should clarify.	The "Data Extraction and Sampling Instructions" have been updated to correct this error.	No change.
111	FDMS	Kaiser Permanente	0019	6/18/2010	Sampling Instructions	In Section 2.0 ("Conceptual Framework for Sampling"), #4 states "Data from interim steps are combined into a detailed data set." We believe the word "steps" should be "sets".	The "Data Extraction and Sampling Instructions" have been updated to correct this error.	No change.

112	FDMS	[none]	0020	6/18/2010	Sampling Instructions	The sampling method appears to be a bit ambiguous. For example, if you sample from the denominator for procedure frequency or SRAE, and you only select 205 members, it is unlikely that your sample will include any of the members for which there was a positive match. However, if you sample from the numerator, then it's both not a random sample and you would have to have an very large plan and/or very poorly performing hospitals in your network to even approach a number from which 205 could be sampled.	No change required. The "Data Extraction and Sampling Instructions" explain that the sampling originates from the Final Stage Data Set.	No change.
113	FDMS	[none]	0020	6/18/2010	Sampling Instructions	Although the documentation asks for "programming code", it seems more appropriate to provide pseudo code (i.e. programming code translated into understandable English).	No changes required. Programming code is required.	No change.
114	FDMS	[none]	0020	6/18/2010	Sampling Instructions	File exchange using encrypted CD seems both archaic and less secure. We suggest using other means (for example, we use a secure web server for most PHI transmissions) as the primary method of file exchange.	The "Data Extraction and Sampling Instructions" have been updated to allow more flexibility (document now allows for secure storage devices beyond CDs).	N/A.

115	FDMS	PerformRX	0021	6/18/2010	OAI	Section 2.2 states "All documentation and responses to questions should reflect the organization's systems and processes that were in place during the reporting period(s) undergoing the data validation review." As the processes used to create reports may include tools where source code management is rudimentary, this proposed requirement may introduce additional complexity to an organization's IT infrastructure to: 1. Maintain multiple versions of IT components (code, data dictionary, etc.) 2. Implement a methodology that readily tracks point-in-time changes to IT components 3. Develop a capability to link to those IT changes and access the variations in code. Additionally, as some reports may result from combining data from service providers with data from the Part D sponsor, systems and processes from multiple parties need to be consolidated as a single flow. It would be preferable to make this proposed requirement effective for CY 2012 to provide organizations the time needed to develop and implement the needed capabilities.	Duplicate of FDMS 0008.	N/A.
116	FDMS	PerformRX	0021	6/18/2010	OAI	Section 2.2 states "The organization is responsible for ensuring that it has established mutually agreeable methods for sharing proprietary and/or secure (PHI/PII) data with the reviewer and that the reviewer complies with all HIPAA privacy and security requirements." The Business Associate Agreement is the standard mechanism for establishing HIPAA compliance obligations with parties receiving PHI. For Part D sponsor data this is the responsibility of the Part D organization. We recommend establishment of standard accepted methods for such transmissions and similar to what occurs for sending secured information to CMS, reviewers should be required to prove to CMS that they have such existing capabilities.	Duplicate of FDMS 0008.	N/A.

117	FDMS	PerformRX	0021	6/18/2010	OAI	Section 5.1 states "For the contract(s) included in this version of the OAI, organizations should provide programming code/source code and example output for computer programs used to calculate the data collected for each of the CMS data measures that are currently undergoing data validation review (as identified in Section 3.3)." Please clarify if a code sample or complete program code is proposed as the requirement. In either approach, since code and all corresponding components (e.g., data dictionary) are proprietary information, a standard provision of providing code must be an obligation with the reviewer that stipulates: 1. The reviewer is responsible for protecting the intellectual property of the providing organization 2. Code will only be used for purposes of the Data Validation efforts 3. The reviewer will indemnify the providing organization if information is otherwise disclosed or used for other purposes	Duplicate of FDMS 0008.	N/A.
118	FDMS	PerformRX	0021	6/18/2010	OAI	Same as comment 5.1	Duplicate of FDMS 0008.	N/A.
119	FDMS	PerformRX	0021	6/18/2010	OAI	Same as comment 5.1	Duplicate of FDMS 0008.	N/A.
120	FDMS	PerformRX	0021	6/18/2010	OAI	Same as comment 5.1	Duplicate of FDMS 0008.	N/A.
121	FDMS	PerformRX	0021	6/18/2010	OAI	Would it be possible for the auditors to view source codes on site (ie. PBM, plan, vendor) and have SME explain. The auditor would not be allowed to have laptop etc. to write source codes down.	Duplicate of FDMS 0008.	N/A.
122	FDMS	PerformRX	0021	6/18/2010	OAI	Please confirm what is meant by captured in your data systems?	Duplicate of FDMS 0008.	N/A.
123	FDMS	PerformRX	0021	6/18/2010	Data Validation Standards	See comments 2.2	Duplicate of FDMS 0008.	N/A.
124	FDMS	PerformRX	0021	6/18/2010	Data Validation Standards	See comments 2.2	Duplicate of FDMS 0008.	N/A.

125	FDMS	PerformRX	0021	6/18/2010	Data Validation Standards	CMS provides a breakdown for the calculation of covered Part D medications per member per month. I t says we will need to provide the coding/logic used to determine the answer. What do you do when you are the vendor receiving files that include only the summary amount per member per quarter? We do not receive the coding logic from the client on how they create the files	Duplicate of FDMS 0008.	N/A.
126	FDMS	PerformRX	0021	6/18/2010	Data Validation Standards	When it reference to -on-site review. Where does on-site mean (i.e. plan level, PBM, vendor, etc.)	Duplicate of FDMS 0008.	N/A.
127	FDMS	PerformRX	0021	6/18/2010	Data Validation Standards	See comments 2.2	Duplicate of FDMS 0008.	N/A.
128	FDMS	PerformRX	0021	6/18/2010	Instructions for Findings Data Collection Form	Any organization providing data should receive the reviewers comments with regard to their findings	Duplicate of FDMS 0008.	N/A.
129	FDMS	PerformRX	0021	6/18/2010	Findings Data Collection Form	Any organization providing data should receive the reviewers comments with regard to their findings	Duplicate of FDMS 0008.	N/A.
130	FDMS	PerformRX	0021	6/18/2010	Sampling Instructions	The line item Coverage Determinations/Exceptions has an incorrect Sampling Unit listed (Case ID). The sampling unit should be Claim ID	Duplicate of FDMS 0008.	N/A.
131	FDMS	PerformRX	0021	6/18/2010	Sampling Instructions	While a CD can be encrypted, it is burdensome to provide information n this manner and expands the risk that organization IP and PHI may be used or disclosed in a manner inconsistent with a BAA or other form of agreement designed to protect such. It is preferable to designate a standard method of exchanging data information that has more robust industry accepted security. Organizations that do not have this capability should not be accepted as reviewers.	Duplicate of FDMS 0008.	N/A.
132	FDMS	PerformRX	0021	6/18/2010	OAI	Concerns: handing over vendor source documents, prep work and the impact to production staff, short CMS implementation time frame, inconsistency among data validation auditors, lack of field knowledge of data validation auditors.	Duplicate of FDMS 0008.	N/A.

133	FDMS	PerformRX	0021	6/18/2010	Data Validation Standards	Concerns: handing over vendor source documents, prep work and the impact to production staff, short CMS implementation time frame, inconsistency among data validation auditors, lack of field knowledge of data validation auditors.	Duplicate of FDMS 0008.	N/A.
134	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010		ACG has examined the proposed DVA requirements closely and believes that CMS' has significantly under estimated the cost burden to MAOs and PDPs of implementing the Part C and Part D Data Validation requirements, especially as released within this package of DVA Standards and Findings Documentation.	The burden estimates have been revised. Please see the updated Supporting Statement for the updated assumptions and calculations.	N/A.
135	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010		ACG is presenting the following comments, many of which relate to clarifying CMS's definitions of specific data categories where ACG believes that without further definition by CMS of the data to be reported, that it will be impossible to properly validate the reported data because the current definition is subject to a wide range of interpretation at the MAO and PDP Sponsor. ACG's comments were developed by ACG's subject matter experts who have many years of hands-on experience supporting MAOs and PDPs to maintain compliance with the regulations that underlie the reporting requirements. We respectively submit that making the clarifications suggested below will enhance MAO and PDP reporting accuracy and allow for expedited data validation.	No response required.	N/A.
136	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	N/A	MAOs and PDPs provide benefits or procure administrative services through a variety of downstream vendors including Individual Practice Associations (IPAs) and behavioral health organizations under Part C, and Pharmacy Benefit Managers (PBMs) for Part D benefits. In many instances, the downstream vendors are producing only a portion of the data that is part of an MAO or PDP plan's reporting.	No response required.	N/A.

137	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	N/A	None of the documents in the PRA Package 10305 address and CMS has not yet opined on, whether a Data Validation Contractor (DVC) can rely on MAO or PDP validation of the data provided by downstream vendors, or whether the DVC must validate the data from downstream contractors.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
138	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	N/A	If the DVC must conduct primary verification of data provided by downstream vendors, especially transaction based data (medical claims and pharmacy claims data,) where that data is only a constituent or subset part of the reported data, the process will be much more costly for the MAO or PDP; at the same time, if downstream contractors are subject to ten's DVC audits (e.g. for PBMs) this process will become untenable for those vendors.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
139	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	N/A	ACG recommends the following standard: For transactional (claim data), where the downstream contractor provides a portion of the data (e.g. IPAs processing claims,) that a DVC rely on, and be required to evaluate an MAO's validation of the data provided by the downstream contractor.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
140	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	N/A	ACG recommends the following standard: For transactional data and non-transactional data where the downstream contractor is the sole outsourcer, the DVC validate data as they would with the MAP	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
141	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	N/A	Following are comments on measure specific criteria contained in the Data Validation Requirements. In some cases comments suggest that CMS to develop more concrete and detailed definitions in order to help enhance reliability, validity, completeness and comparability of data that is received in the initial cycles of data validation.	No response required.	N/A.

142	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Validating data related to all these elements may be difficult using the current loose definition of services provided. MAOs may opt to pay for a particular service that is not covered under original Medicare requirements as a value added benefit, as a benefit exception, or for a variety of other reasons. MAOs claims payments systems generally do not note whether a service is traditionally covered by Medicare or not, but is being covered by the Plan on an exception basis. ACG recommends that CMS provide clarification in the form of a more specific definition of the services to be included in the values in this reporting, encompassing all benefits provided to MAO enrollees.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
143	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Almost all SRAEs occur in the hospital setting and, because of the sensitive nature of the data; many hospitals do not willingly provide it to MAOs. DVCs could test a MAO's policy and procedures for identifying SRAEs as part of its Quality of Care review process, but would still not be able to assess completeness of reported data. It is unlikely that MAOs will have complete SRAE data in the absence of contractual requirements that hospitals provide it. ACG recommends that consideration be given to delaying the implementation of measure specific requirement 5 while CMS develops a regulation requiring that MAOs's contracts with hospitals contain a clause requiring the report of SRAEs.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
144	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	As currently construed the term "in the network" is loosely defined. Since the data is reported at a contract level and not a county level as with MAO Health Service Delivery Tables, further definitions regarding counting would also be useful.	No response required.	N/A.
145	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	MAO's differently construe "in the network" to include 1) contract signed, pending credentialing review process, 2) provider contracted and completely through credentialing process and eligible to treat members, 3) in process with credentialing committee.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.

146	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Further, for staff model or group practice MAO delivery systems, there is no definition around whether the numbers reported are to count full time equivalents (FTEs) or individual practitioners.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
147	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	If a provider has multiple offices (e.g. in multiple counties) CMS should define whether this provider should be counted only once (which is assumed since reporting is at the contract level.)	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
148	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	ACG recommends further definition be developed for the purpose of testing “continuously” part of the network.	No response required.	N/A.
149	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	That providers be contracted on Day 1 and Day 365 without a lapse in availability of service provided	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
150	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	That if a provider’s contract has expired, but been extended during negotiations, that provider also be counted.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
151	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	That is a provider has been sanctioned, or served with termination notice but the internal review is still ongoing and the provider has not been finally terminated that the provider be counted.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
152	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	ACG recommends that CMS clarify the definition of “accepting new patients” for this reporting category. Physicians may be accepting new patients generally or only for referred patients etc. ACG recommends that this count include both.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.

153	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	ACG recommends that CMS clarify the definition of a “Hospital”. Does the definition of Hospital include: acute care only, specialty hospitals, CORFs, Partial Stay institutions, outpatient only facilities, etc?	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
154	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Grievances are a measure where CMS appears to be concerned regarding the wide variance in reported numbers. The current Validation Standard and related sampling instructions focus on sampling grievance data only. ACG recommends that CMS add to the Grievance sampling criteria that DVCs audit a sample of Part C Customer Service logs to validate grievance counts under the expected numbers rubric. Without testing the customer service logs is a chance that MAOs will receive validation for a total number of Part C grievance data remains incorrect because it only samples data within the MAO’s or PDP’s actual Grievance database, not actual complaints, especially oral, filed with the MAO or PDP.	CMS considered this approach in developing the DV standards and determined it would add an unacceptable resource burden to the process	No change.
155	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	The use of the term “final decision” needs clarification for proper recording and accurate testing. Although re-openings are defined in Managed Care Manual Ch.13, 130, as a remedial action to taken to change a final determination, MAO plans use this process to manage cases where an adverse determination was issued because requested information was not received, and MAO plans subsequently receive the information. Without clarification that these cases are excluded, MAOs might include them. Even with clarification, the data validation procedure should include assessing if the MAO has classified these cases correctly	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
156	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	ACG recommends clarification regarding Sub Element 5c. The statement that ODs “does not combine fully favorable claims determinations for the same approved services” is vague. With this statement, CMS may be trying to avoid double counting approved final authorizations and paid claims.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.

157	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	As written, Sub Elements 5b and 5k potentially conflict. 5b asks MAOs to include all ODs covered by Medicare and Medicaid, yet 5k allows MAOs to exclude ODs where there is no member liability. In some States, the Medicaid coverage for duals effectively shields the member from all liability, as Medicaid picks up what Medicare does not. ACG recommends that CMS clarify whether ODs should be counted in 5K in instances where a State picks up the cost sharing balance for dual eligible Medicaid members.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
158	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Currently, CMS currently requires that such complaints be reported under each contract an MAO or PDP has if the specific contract can not be identified. One example would complaints received during a canceled enrollment or “beneficiary did not complete” enrollment be reported since they are not tied to a specific contract. Current guidance may significantly inflate the number of actual complaints, especially for large national plans if the actual contract is not identified, which can often be the case. As such there is potentially built in bias in reported numbers. ACG recommends that CMS change this requirement to allow the MAO or PDP to record the complaint once, for one contract within the state where the complaint occurred, if the actual contract can not be identified, thereby enhancing the “comparability” of the supplied data and simplify testing.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
159	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Some states to not require appointment of agents. ACG recommends that 4b read "all licensed agents who are under contract agreement to sell on behalf of the contract and appointed during the reporting year, except in states that do not require appointment"	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
160	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	ACG believes that the term “Complaint” is insufficiently defined to effectively support comparable data. Complaints may range from "Activities which mislead, confuse, or misrepresent the MAO”, to the fact that an agent was late for an appointment, or falsified information on an application. ACG recommends that CMS define what types of “Complaints” are to be included in the report values and tested by the DVC.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.

161	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	ACG recommends that CMS clarify in the Technical Specifications and DVA Standards whether revocation of selling privileges is reported only when it is permanent or when permanent or temporary (as when going through retraining.)	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
162	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Dates of LTC enrollment, MTM enrollment and MTM opt-outs could occur multiple times for the same enrollee within the time period. ACG recommends that CMS clarify and define whether beneficiaries with multiple opt-outs (over time) should be counted once or per opt-out. (Assuming re-enrollment)	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
163	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Grievances are a measure where CMS appears to be concerned regarding the wide variance in reported numbers. The current Validation Standard and related sampling instructions focus on sampling grievance data only. ACG recommends that CMS add to the Grievance sampling criteria that DVCs audit a sample of Part C Customer Service logs to validate grievance counts under the expected numbers rubric. Without testing the customer service logs is a chance that MAOs will receive validation for a total number of Part C grievance data remains incorrect because it only samples data within the MAO's or PDP's actual Grievance database, not actual complaints, especially oral, filed with the MAO or PDP.	CMS considered this approach in developing the DV standards and determined it would add an unacceptable resource burden to the process	No change.
164	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	Low Income Subsidy (LIS) status changes frequently and will impact whether MAPD and PDP quarterly reporting is accurate even though it reflected the best available information when the report was filed. For example, a non-LIS member files a grievance on May 28 with the grievance closing on June 3, but in August there is a retroactive change to the member's LIS status. ACG requests that CMS provide guidance as to how this situation should reported by the MA-PD or PDP, i.e. as an LIS member or not.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.

165	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Data Validation Standards	“Pharmacy Transactions” should be better defined. Does it include or not include EA drugs transactions?	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
166	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Sampling Instructions	Sample Sizes to not appear to be appropriately stratified for smaller plans.	The "Data Extraction and Sampling Instructions" have been updated to indicate that stratified data is an option. This is left to the reviewer's discretion.	No change.
167	FDMS	ATTAC Consulting Group, Inc	0022	6/18/2010	Sampling Instructions	Sampling instructions and testing overall do not reflect the challenges of a delegated services or processing model operated by many MAOs and PDPs (e.g. IPAs, PBMs) where source data may not be easily obtainable.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
168	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	N/A	Rather than validating all these measures every year, organizations would like to see a more pointed audit that utilizes a phased approach. Perhaps data validation could be completed on a portion of the measures one year and a different portion the following year.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
169	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	N/A	Part D data validation will commence around March 1, 2011 and the data validation audits are expected to occur each year over a three-month period. However, measures like 2010 Benefit Utilization aren’t due until August 2011. Please clarify how the data will be validated if the audits take place in March?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
170	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	N/A	Regarding the timing of the validation audits, we suggest conducting these after the bid submission due date. Since some of the work on the bid creation feeds into our reporting data (particularly benefit utilization), that work would then be completed by the time of the audit and not place undue burden on plans while they are focusing on bid submission.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

171	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	Supporting Statement	Please clarify whether contracts that are non-renewing for CY2011 will be required to undertake a data validation audit for data reported in 2010	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
172	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	Supporting Statement	Based on our analysis, CMS has grossly underestimated the staff time and expense of these audits. Our estimates indicate it will take 5 to 10 times the staff time as CMS' 120 hour estimate. The vendors we have spoken to estimate their staff time will be 2 to 3 times CMS' estimate of 206 hours per contract. Finally, based on quotes we've received from audit vendors, the cost to procure and support the auditor is anywhere from 5 to 10 times higher than CMS' estimate of $5,177 per contract	The burden estimates have been revised. Please see the updated Supporting Statement for the updated assumptions and calculations.	N/A.
173	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	OAI	Indicates that a separate OAI must be completed for each contract if the information provided varies by contract. We suggest formatting the OAI in such a way as to accommodate the inclusion of more than one contract. This would be a relatively simple change to the setup of the document and would decrease the burden on organizations who will otherwise have to fill out a separate version for every contract they have.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
174	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	Findings Data Collection Form	States the reviewer will share findings with the organization and then submit the completed Findings Data Collection Form to CMS who will process the measure- or data element-level findings for each measure's standards to derive an overall "Pass" or "Not Pass" determination.	No response required.	N/A.
175	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	Findings Data Collection Form	Similar to other regulatory processes (CMS/OIG audits), organizations should have an opportunity to respond to or dispute the reviewer's findings.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

176	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	Findings Data Collection Form	There is no information as to what constitutes "Pass" and "Not Pass", the ramifications of receiving a "Not Pass" and what recourse organizations have in that event. The document suggests this will be an overall determination. What is meant by "overall" since some measures are at the PBP level and some at the contract level?	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
177	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	Findings Data Collection Form	We suggest that CMS prioritize the measures for purposes of "pass" and "not pass". For example, there are 138 benefit utilization measures –we suggest ranking the measures and requiring a smaller number of measures that CMS considers higher priority be met to constitute a pass rather than all measures.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
178	FDMS	Blue Cross Blue Shield of Minnesota	0023	6/18/2010	Sampling Instructions	In comparison to other types of audits (for example CMS audits, NCQA) the sample sizes are very large. This is burdensome for plans as well as auditors and we feel these sample sizes could be reduced substantially while maintaining the integrity of the validation.	No change required.	No change.

179	FDMS	America's Health Insurance Plans	0024	6/18/2010	Standards for Selecting a Data Validation Contractor	Contractor Selection. In the Supporting Statement, CMS explains that each plan sponsor will be required to enter into agreement with a data validation contractor that meets CMS' standards, which will describe the minimum qualifications, credentials, and resources that the contractor must possess. During the CMS 2010 Medicare Advantage and Prescription Drug Plan Spring Conference (2010 Spring Conference), CMS indicated that CMS will provide training this fall for plan sponsors and interested contractors and that each plan sponsor will be responsible for documenting its contractor selection process, including how the sponsor determines that the contractor chosen meets the CMS standards. To serve CMS' principal goal for the data validation program, which is to ensure that data for monitoring and performance measurement are "reliable, valid, complete, and comparable among sponsoring organizations," we strongly urge the agency to certify contractors that meet CMS requirements and to make a list of these contractors available to plan sponsors. By conducting a centralized review of contractors, CMS or a contractor on the agency's behalf will be best positioned to accomplish uniform and accurate application of CMS standards, promote consistent data validation reviews by contractors, and ensure availability of a sufficient number of qualified contractors to conduct data validation for all plan sponsors. In addition, the agency's knowledge of the contractors as a result of the certification process will position CMS to evaluate the potential impact of contractor performance on data validation results, which will be particularly important in the first year of implementation when CMS, plan sponsors, and contractors will be gaining experience with the new process. This approach would be consistent with the conduct of the Health Outcomes Survey (HOS) and CMS' plans for the Medicare Consumer Assessment of Health Plans Survey (CAHPS). As the agency explained in the preamble to its October 22, 2009 (74 FR 54633) proposed regulation for the MA and Part D programs and confirmed in the preamble to the April 15, 2010 final regulation (75 FR 19677), MA organizations will be required to choose from a CMS list of	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

180	FDMS	America's Health Insurance Plans	0024	6/18/2010	Standards for Selecting a Data Validation Contractor	If CMS does not adopt AHIP's recommendation for CMS contractor certification and plan sponsors remain responsible for the contractor selection process, we recommend that CMS provide clear, detailed guidance about the agency's standards for qualified contractors and the documentation plan sponsors must maintain to meet CMS' expectations for demonstrating how they have applied these standards. We urge CMS to issue these requirements as soon as possible, because plan sponsors are already working to identify potential contractors to be prepared to contract for timely pre-assessment and data validation reviews.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
181	FDMS	America's Health Insurance Plans	0024	6/18/2010	Standards for Selecting a Data Validation Contractor	We also recommend that CMS conduct a training session for plan sponsor staff involved in contractor selection to promote consistent understanding of the requirements.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
182	FDMS	America's Health Insurance Plans	0024	6/18/2010	Standards for Selecting a Data Validation Contractor	Further, we recommend that CMS develop a strategy for addressing the possibility that qualified contractors may not have sufficient capacity to accommodate contracting with all plan sponsors for simultaneous reviews.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

183	FDMS	America's Health Insurance Plans	0024	6/18/2010	Standards for Selecting a Data Validation Contractor	To prepare for CMS desk and onsite program audits based upon CMS' Monitoring Guides, it is common for plan sponsors not only to conduct internal activities to review compliance with CMS requirements but also to engage contractors to conduct independent reviews. As plan sponsors prepare for implementation of the data validation reviews, they are interested in following similar practices. As CMS establishes standards that contractors must meet to conduct Part C and Part D data validation, we recommend that the agency explicitly provide that a plan sponsor may utilize the same contractor to conduct both pre-assessment and data validation reviews. CMS indicated at the agency's 2010 Spring Conference that such arrangements with qualified contractors would be permissible, and we believe that this approach could not only facilitate plan sponsor efforts to enter into agreements with contractors but also has the potential to facilitate data validation by familiarizing the contractor with plan sponsor systems in advance of the data validation review.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

184	FDMS	America's Health Insurance Plans	0024	6/18/2010	N/A	It is not uncommon for plan sponsors to contract with PBMs and other delegated entities to carry out functions that may include collecting and maintaining data that are used to satisfy Part C and/or Part D reporting requirements and that would be included in data validation reviews. Since a single PBM or other delegated entity may contract with multiple Part C and Part D plan sponsors, it will be administratively complex and significantly more burdensome for these delegated entities to work with differing data validation contractors selected by each plan sponsor. To address this situation, we recommend that CMS provide in the guidance that, for data maintained by delegated entities, it is permissible for plan sponsors, at their election, to rely on reviews performed by qualified data validation contractors under contract to the delegated entities. We also recommend that CMS specify, if such an election is made, how reporting of results from multiple data validation contractors for a single Part C or Part D contract number would be accomplished, and we urge CMS to develop these requirements in consultation with Part C and Part D plan sponsors. We would be interested in engaging in discussions with CMS to assist the agency in identifying and resolving practical issues that could merit consideration.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

185	FDMS	America's Health Insurance Plans	0024	6/18/2010		While data for a number of measures under the Part C reporting requirements are due by February 28 of the following year (e.g., provider network adequacy, plan oversight of agents), several Part C measures have a reporting deadline of May 31 of the following year (e.g., procedure frequency, serious reportable adverse events, SNPs care management) and Part C benefit utilization data are due by August 31 of the following year. In addition, Part D data on long-term care pharmacy utilization are due by June 30 of the following year. The Supporting Statement and accompanying Appendices do not address how the data validation process for these measures would be coordinated with the data collection deadlines. However, CMS noted at the agency's 2010 Spring Conference, that for "measures with submission dates of 5/31, 6/30, and 8/31, an extension for data validation reviews and submission of findings to CMS is being considered." (See CMS presentation on "Part C & D Reporting Requirements and Data Validation," slide 10.)	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

186	FDMS	America's Health Insurance Plans	0024	6/18/2010		Since a later data validation data collection period than the proposed time frame of approximately March – May would be better aligned with the deadlines under the Reporting Requirements, we recommend that CMS reconsider the March – May time frame for annual data validation data collection and submission and establish a later period to provide for consistent coordination with the deadlines under the Reporting Requirements across all measures. If CMS does not adopt this recommendation, we recommend that the agency establish specific timeframes for validation of data for each measure that has a deadline of May 31 or later under the Part C and Part D Reporting Requirements. Since a later data validation data collection period than the proposed time frame of approximately March – May would be better aligned with the deadlines under the Reporting Requirements, we recommend that CMS reconsider the March – May time frame for annual data validation data collection and submission and establish a later period to provide for consistent coordination with the deadlines under the Reporting Requirements across all measures. If CMS does not adopt this recommendation, we recommend that the agency establish specific timeframes for validation of data for each measure that has a deadline of May 31 or later under the Part C and Part D Reporting Requirements.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

187	FDMS	America's Health Insurance Plans	0024	6/18/2010		In response to a question at CMS' 2010 Spring Conference, the agency indicated that CMS would evaluate the first year of experience with the data validation initiative before considering whether the validation program might move to requiring submission of data on a subset of measures rather than all measures. While AHIP appreciates that CMS has conducted pilot testing of the data validation program, the agency has indicated that only one large MA-PD organization and one large PDP participated in this testing. As with any new program, it is likely that as all MA and Part D plan sponsors begin implementation, a variety of questions and operational issues will arise as plan sponsors, data validation contractors, and CMS gain experience with the data validation requirements.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.
188	FDMS	America's Health Insurance Plans	0024	6/18/2010		Consequently, AHIP recommends that for the first year, CMS revise its approach to focus reporting on a subset of measures to permit all parties to gain an understanding of the process and allow an opportunity for any needed adjustments to be put in place. We also recommend that as CMS evaluates the results, the agency take into consideration that the results may be affected by start-up issues. In addition, for the future, we recommend that CMS rotate validation of measures over a three year timeframe, rather than requiring validation of the entire set of measures in order to make the best use of CMS and plan sponsor resources. We believe that such an approach would permit CMS to complete timely analysis of the data validation results and utilize this information effectively for oversight purposes.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

189	FDMS	America's Health Insurance Plans	0024	6/18/2010		In the Supporting Statement on page 5 and in Appendix 1 (see below) CMS indicates that the agency will "process the measure-level or data element-level findings for each measure's standards to derive an overall 'Pass' or 'Not Pass' determination." At CMS' 2010 Spring Conference, the agency explained that scoring and thresholds for these determinations are under development and would be the subject of future CMS guidance. We support the agency's intent to provide information to plan sponsors about the methodology CMS will utilize to arrive at "Pass" and "Not Pass" determinations. We recommend that the forthcoming guidance provide a detailed explanation of the methodology and that CMS provide an opportunity for plan sponsor review and comment prior to finalizing the methodology to allow the agency to consider relevant operational and implementation issues.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the data validation training (expected Fall 2010), and the data validation Manual. Regarding the Pass/Not Pass Determination logic, CMS plans to share this logic with industry once it is completed (this logic does not require OMB clearance and will be shared separately).	N/A.
190	FDMS	America's Health Insurance Plans	0024	6/18/2010	Standards for Selecting a Data Validation Contractor	The third paragraph under Section 1.1 states that "The reviewer will share these findings with the organization and then submit the completed Findings Data Collection Form to CMS, who will process the measure- or data element-level findings for each measure's standards to derive an overall "Pass" or "Not Pass" determination." To promote consistent understanding, we recommend that CMS revise this language in the instructions to clarify that the contractor will be required to conduct an exit interview, as well as share findings with the plan sponsor, and that contractor findings submitted to CMS should note any findings with which the plan sponsor disagrees and the reason for the disagreement. It appears the language in the Appendix is intended to reference these well-established steps that are commonly followed in CMS audits.	Policy questions will be addressed separate from the documents undergoing OMB clearance. These questions will be addressed in future industry communications, the Data Validation Training (expected Fall 2010), and the Data Validation Manual.	N/A.

191	FDMS	America's Health Insurance Plans	0024	6/18/2010	Data Validation Standards	In the Measure-Specific Criteria, items 5. and 8. list the criteria for determining whether the MA organization accurately calculates the total number of organization determinations and reconsiderations, respectively. Criteria 5k. and 8f. indicate that the calculation excludes organization determinations and reconsiderations, respectively, where there is no member liability. However, in the Medicare Part C Reporting Requirements Technical Specifications, Version Date: June 3, 2010, the specifications for measure "6. Organization Determinations/Reconsiderations," no longer include this statement, although it appeared in the previous version (Version Date: February 24, 2010). For clarity, we recommend that CMS revise the Part C Reporting Requirements Technical Specifications to restore the statement. We also recommend that CMS conduct a review to ensure that the data validation standards are consistent with the June 3 reporting requirements for all measures.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
192	FDMS	America's Health Insurance Plans	0024	6/18/2010	Sampling Instructions	In section "2.0 Conceptual Framework for Sampling," CMS notes in item 2. that "[m]any organizations have analytic warehouses where data is cleansed and put into database structures to support analysis." Subsequently in section 2.0 and in item "4. Create 'Source Samples(s)'" of section "3.0 Sampling Process Detail," CMS indicates that source samples will be drawn from either the plan sponsor's data warehouse or operational systems. Consistent with the related schematics, it appears that this language is intended to indicate that if the plan sponsor has established a data warehouse, the source sample will be drawn from the warehouse. If not, the source sample will be drawn from the operational source systems. We recommend that CMS revise the language in the referenced sections to clarify that this is the case.	The "Data Extraction and Sampling Instructions" have been updated to add clarification.	No change.

193	FDMS	Health Net, Inc.	0025	6/18/2010	Data Validation Standards	This methodology would result in an incomplete count of HRA completion. HRA completion for members that were enrolled at the end of the reporting period may have completed the HRA subsequent to the reporting period given the 90 day window allowed for this requirement. Therefore it is recommended that either 1) Data Element 13.3 extends the measurement period to 90 days after the reporting period so that completion of an HRA within the 90 day required time frame is included in this measure for all newly enrolled SNP members whose effective date of enrollment occurred during the reporting period OR 2) The requirement that Element 13.3 be a subset of Element 13.1 is removed so that all HRAs completed during the reporting period be included in this data element regardless of the effective date of enrollment.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
194	FDMS	Health Net, Inc.	0025	6/18/2010	Data Validation Standards	Appendix 3 (p.9) Criteria 4 states: 4. Organization accurately calculates the total number of surgeries, including the following criteria: a)Includes all surgeries with dates of service that occur during the reporting period; b)Includes only surgeries that occur in an acute hospital setting(Data Element 3:1) But 5.b. states: c) 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). Our Comment: There will be no standardization or ability to trend over time or across plans if events from prior periods are included. The same direction is provided for HACs.	The measure-specific criteria in both the "Data Validation Standards" and the "Findings Data Collection Form" have been updated to reflect the most recent updates to the Technical Specifications documents (June 2010 versions).	No change.
195	FDMS	Health Net, Inc.	0025	6/18/2010	Sampling Instructions	Will CMS provide alternatives to submission format (other than by CD)?	The "Data Extraction and Sampling Instructions" have been updated to allow more flexibility (document now allows for secure storage devices beyond CDs).	No change.

196	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: After extracting sample data sets for some measures and extracting the entire data set or “census” for other measures, it was determined that extraction of the entire data set did not add an undue burden to the organization undergoing review.	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: When possible, the data validation reviewer should obtain the census of data records used to report a measure. This will ensure that the source through final stage data sets support the data reported via HPMS. An exact determination of compliance with validation standards can be determined using the census, instead of relying on an estimate generated by sampling. The use of random sampling should be left to the discretion of the data validation reviewer and should be limited to situations where pulling all records for a measure will create too heavy a burden on the organization. In addition, the "Data Validation Standards" have updated references of "sample data" to "census or sample data."	Net decrease.
197	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: Using sample data to check manual processes or to check for errors that occur relatively infrequently may require larger sample sizes than those currently outlined in the *Sampling Instructions*.	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: Allow data validation reviewers the flexibility to request sample data sets larger than the sizes prescribed in the April 2010 *Sampling Instructions* (i.e., more than 150 or 205 records) if additional data are required to complete the review.	Net decrease.
198	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: It was no more difficult to pull data for the entire year vs. pulling sample data for only one reporting period (e.g., one quarter).	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: The data validation reviewer should select and review the entire year’s data for a measure, despite the measure’s reporting frequency requirements (e.g., quarterly, bi-annual). This will simplify the process for the data validation reviewer and allow thorough examination of all reported data, eliminating issues related to data seasonality.	Net decrease.

199	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: While two to four gigabyte flash drives were sufficient for collecting data for the pilot tests, larger external drives may be needed for data covering multiple contracts and data measures.	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: The data validation reviewer should work with the sponsoring organization prior to the site visit to determine file sizes and ensure that data storage requirements are sufficient for data transport.	No change.
200	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: It was more likely that if the source data relied on a transactional database where records are often updated, the source files were not archived. Similarly, many of the intermediate files created using query programs were not archived.	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: Ensure that copies of source, intermediate, and final stage files are saved so that reporting requirements can be re-generated at any given time for validation purposes (e.g., so that counts in the files match HPMS reported counts).	No change.
201	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: Additional data fields should have been included in the organizations' sample data sets, in order to assess the accuracy of their reported data.	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: An organization's measure report owners/data providers should familiarize themselves with the standards and criteria included in the "*Data Validation Standards"* document. This will ensure that the report owners/data providers are prepared to pull the appropriate data fields necessary during the sampling process. The data validation reviewer should also reference this document as needed when conducting the on-site review to confirm that the required data fields are provided.	No change.
202	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: Without intermediate data sets, it may be difficult for the review team to determine whether data sets were extracted properly (e.g., tables may have been joined incorrectly, or records were included/excluded improperly).	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: For more complex measures that draw data from multiple databases or intermediate data source files, a sample or census from each of the intermediate data sets will aid the data validation reviewer in determining if tables are being joined properly.	No change.

203	Pilot Finding	CMS	N/A	6/16/2010	Sampling Instructions	CMS Pilot Finding: An organization's security software may interfere with transferring data to an encrypted flash or hard drive.	The "Data Extraction and Sampling Instructions" have been updated to include the following CMS recommendation: The reviewer and organization should confirm that the type of device used to transfer data will be compliant with the organization's systems.	No change.
204	Pilot Finding	CMS	N/A	6/16/2010	OAI	CMS Pilot Finding: The level of detail in the documentation provided by the pilot organizations varied.	The "Organizational Assessment Instrument" have been updated to include the following CMS recommendation: Include a data dictionary template as a reference to help organizations more effectively prepare their documentation for reviewers. For example, the dictionary template could illustrate pertinent content such as data field name, data field description, and code definitions.	No change.
205	Pilot Finding	CMS	N/A	6/16/2010	OAI	CMS Pilot Finding: There were gaps in the documentation provided, and it was not always possible to replicate a data report that was submitted to CMS via HPMS.	The "Organizational Assessment Instrument" have been updated to include the following CMS recommendation: Include instructions for the organizations to reference the CMS Reporting Requirements Technical Specifications to ensure documentation is provided for all data elements. Include a list of minimally required data fields (e.g., Case ID, Case Receipt Date, Case Resolution Date) for each measure to ensure that the appropriate data and level of detail is being captured for accurate reporting.	No change.