DV General Comments for 60-Day Comment Period

Organization	DV Area	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
Advent Advisory Group (a6li)	Likert Scale	Standards 1c, 1d, 1e, 1h and 2 e: 1.) Why were only the specific standards listed above chosen to be impacted by this change? For instance, why was Standard 3a not included in this proposal? 2.) It appears that Part C and D Grievances, based on the documentation provided, are no longer at 0% threshold for error. Is this correct? If so, this seems to run counter to CMS's goal for differentiation in scores, as having those measures set for 100% accuracy appeared to be a major differentiator in scores across Advent's book of business, and we would assume across all clients undergoing Data Validation review. 3.) It is our understanding that CMS intends that this scoring change would be put into effect starting with the 2017 DV season (for 2016 calendar year data). As this is a major change to scoring, and will require deeper understanding by all the SO's, training within the SO's and for all DV clients, we would kindly propose that should these changes be put into place, that they do not become effective until the 2018 DVseason (for 2017 calendar year data). This will allow all SO's and client to get up to speed and fully understand the scope of these changes prior to them becoming effective. All of our proprietary tools and documentation will need updating to accommodate these changes and allowing for more time and education on CMS's expectations will ensure all SO's are implementing the changes in the same manner.	N/A	Some standards are better scored by a "pass-fail" or "yes-no" response. The standards scored using the Likert Scale require sampling and are fairly specific. We believe that Standard 3a is more generic and is better suited for an overall assessment which does not fit the Likert Scale 1-5 format. That is our opinion at this time but we could reconsider this in the future.
Medical Mutual of Ohio (rdwh)	Cover Page	The cover page cites Version 7, while header and footers on subsequent pages cite Version 6.0.	N/A	CMS will correct the cover page.
MMMHC (85e4)	Cover Page	General comment: Document header in each page has not been updated (references Appendix B version 6.0).	N/A	CMS will correct Appendix B.

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Ucare (71eq)	Scoring	UCare does not support revising the scoring methodology for some standards and sub-standards from a binary scale (i.e., Yes/No) to a five-point Likert-type scale. This adds additional complexity to the data validation process.	N/A	CMS respectfully disagrees. We believe that using the Likert Scale provides a more rigorous scoring methodology that also offers greater feedback to plans about the areas that need improvement versus areas in which they are performing well.
United Healthcare (tc7y)	Supporting Statement: Five Point Likert Scale	United seeks clarification from CMS regarding whether this proposed revision is applicable to only the 2017 and 2018 DV collection periods, or if it also applies to the 2016 DV collection period. If the proposed five-point Likert-type scale is not adopted for the 2016 period, United would ask for further clarification on whether the current scoring methodology will be applicable to the 2016 DV collection period instead. Should CMS make this change, we understand that the current 100% accuracy threshold for the individual grievance categorization sub-standard measure to receive a 5-star rating would change to a 95% threshold. If that is not the case, then we request additional clarification regarding the weighting/scoring at the standard level, reporting section level, and the contract level for the following scenarios under the five-point Likert-type scale: Display Measures and measures used for Star Ratings. We strongly encourage CMS to consider adopting the five-point Likert-type scale starting with the 2016 DV collection period, which would correspond to the DV audit occurring in 2017.	Additionally, we would encourage CMS to consider applying the five-point Likert-type scale at the standard and sub-standard levels to all reporting sections and data elements.	CMS does not intend to change the proposed methodology to use the Likert Scale at all standard and sub-standard levels. Some changes toward this end might be considered in the future.

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United Healthcare (tc7y)	Toolkit	There are many references to a toolkit throughout the Coverage Determinations and Reconsiderations. Specifically, Appendix L states "Toolkit for universes for sponsor data validation should be used by the reviewer when validating plan data. The toolkit provides a guide on which data elements to identify from SO data, to validate data submitted in HPMS for this reporting section."	We respectfully request that CMS release a copy of the toolkit specifications and QC steps to allow plans the opportunity to review.	The toolkit will be released with the final DV document.
BCBS Association (8rlt)	Submission Deadline	Also one plan noted that the early February data submissions may be a challenge for plans and lead to more resubmissions.	N/A	While this comment is out of scope for the DV PRA. CMS will consider this comment.
BCBS (ymqk)	FDCF	The CMS Supporting Statement indicates that for the CY2017 and CY 2018 data collection periods, the agency is proposing to revise the Findings Data Collection Form (FDCF) by changing the scoring of six standards (i.e., 1c, 1d, 1e, 1g, 1h, & 2e) from a binary scale to a five-point Likert-type scale. CMS expects that this change will improve the precision of the data validation scores by increasing the overall variation in total scores among Medicare Advantage Organizations (MAOs) and Prescription Drug Plans(PDPs). While we appreciate that the agency is proposing this modification with the intention of improving the precision of scores, we believe additional information is necessary to permit a comprehensive review of the change.	For example, we would appreciate receiving from CMS our most recent data validation scores for the six impacted standards, calculated under both the existing and revised scoring methodology. We believe data along these lines would permit HCSC to fully evaluate the proposed change and provide the most informed and meaningful feedback to CMS.	At this time, CMS is not able to provide your current DV scores in the new methdology. However, you are able to retrieve your current DV scores in HPMS.

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Perform Rx (8l4s)	Audit Training	Data Validation audits are performed by external contractors who are compensated by plan sponsors. CMS's current data validation auditor training is not at all rigorous. This training is at an individual level and in its current form does not represent excellence or competence on the part of the audit firm. To date, we understand that CMS does not have a process to certify specific audit contractors. While most firms are reputable, there is nothing to prevent less-than-qualified audit firms from conducting such audits. We believe that CMS should strengthen the data validation audit process by requiring higher auditor training standards.	N/A	At this time, CMS has committed to changing the DV questions anually and creating more complex questions. CMS shares this concern and is working towards this goal. If you have specific suggestions to assist us please feel free to provide them.
Perform Rx (8l4s)	Consistent Auditor Interpretation	In order for the data to be reliable and valid, consistent audit interpretation is required amongst auditors. PerformRx has experienced inconsistency across data validation auditors first hand. For example, for the Medication Therapy Management (MTM) data validation, we experienced one auditor who interpreted that we are not permitted to count the same recommendation twice to a different provider, regardless of quarter. Conversely, another data validation auditor interpreted that a recommendation could count twice if the recommendation was made in a separate quarter. As illustrated by this example, the same type of event may or may not be reported, depending on the particular interpretation of the auditor. Reporting by Part D sponsors therefore may not be a true measure of their services (i.e., underreporting or overreporting). Further, comparisons among sponsors may not be valid if data is reported differently due to data validation auditors' varying interpretations.	N/A	This comment is out of scope, and there is a procedure if you disagree with a DV auditor's assessment, and your comments/concerns can always be sent to the respective CMS mailboxes like DV or Part D plan reporting. **CMS Action:** No action taken.

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Perform Rx (8l4s)	Reporting Requirements	Would CMS be willing to release final reporting requirements earlier in the year and on a consistent basis?	An earlier and consistent release would be especially helpful when there are significant changes. This would enable Part D sponsors and PBMs sufficient time to adjust and finalize logic and make other needed systems changes. This could lead to higher validation scores across the industry and reduce administrative burdens on CMS.	At this time, this comment is out of scope regarding Reporting Requirements. However, CMS works to release this information as soon as possible.

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Perform Rx (8l4s)	Post-Validation Guidance and Best Practices	Post-validation guidance and best practices from CMS would be beneficial for Part D sponsors and PBMs to know how to adjust reporting to better meet CMS' reporting requirements.	PerformRx recommends, for example, that CMS issue a Best Practices and Common Findings memorandum, and CMS job aids, for the data validation audits similar to the memoranda that CMS issues for CDAG and ODAG audits. Additional training and communication from CMS would also be welcome to strengthen the process.	CMS agrees and this year we have released a "Best Practices" memo and we can consider doing this annually if the industry finds this helpful.

Grievances for 60-day Comment Period

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
BCBS Association (2n4c)	Appendix 1 Data Validation Standards_Version 3_061516.508.pdf: Pages 3 & 4	There appears to be some contradiction in that Appendix 1 Data Validation Standards_ Version 3_061516.508.pdf: Page 4 in the table about REPORTING SECTION CRITERIA for Part C grievances, #6.j states “Excludes expedited grievances,” but #5 item c and #8, item a.iii of the same section reference the inclusion of expedited grievances. Additionally, the Medicare Part C Plan Reporting Requirements Technical Specifications, item # 5, Page 9, indicates that the expedited grievances should be included in the reporting.	We recommend CMS confirm when/if expedited grievances should be included in the reporting.	CMS agrees and will update Appendix 1 and Part C RR & TS documents.
Ucare (71eq)		Align the Part C and D Grievance reporting accuracy threshold with the accuracy thresholds for the other reporting section so that all have a 90% accuracy threshold.	N/A	This will change with the new Likert Scale methodology.

SOA for 60-day Comment Period

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
Medical Mutual of Ohio (rdwh)	Page: 35, Section: Reporting Section Criteria #4	Medical Mutual would like clarification regarding the timeframe for the following criteria: "g" cites "previous calendar year" as the timeframe as follows: Properly identifies and includes the Agent/Broker Training Completion Date for the previous calendar year products. (Ex. If the current year is 2016 it would be CY2015 products, etc.) "h" cites "previous year" as the timeframe as follows: Properly identifies and includes the Agent/Broker Testing Completion Date for the previous year products. (Ex. If the current year is 2016 it would be CY2015 products, etc.)	N/A	CMS agrees and will update.
United Healthcare (tc7y)	SOA	Following the suspension of reporting Sponsor Oversight of Agents in 2017, we request clarification whether CMS plans to remove it from the DV occurring in 2017. Removing Sponsor Oversight of Agents from the DV occurring in 2017 might reduce costs incurred for the DV occurring in 2017 as well as any costs associated with any pre-assessment activity for this reporting section.	N/A	The SOA 2016 data collection will be data validated in 2017. The SOA 2017 data collection will not be included in the 2018 data validation.

HRA for 60-day Comment Period

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
Kaiser (kzdr)	E13.1: Number of New Enrollees	DVA E13.1a doesn't specify a minimum duration of enrollment for a member to count as a new enrollee while the technical specifications, April 22 version. state the member must be enrolled continuously for more than 90 days after the effective date of enrollment to qualify as a new enrollee	N/A	RSC 4.a. will be revised to state: Includes all new members who enrolled during the measurement year, and includes those members who may have enrolled as early as 90 days prior to the effective enrollment date as they will be considered eligible for an inital HRA for the year in which the effective enrollment date falls.

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
Kaiser (kzdr)	E13.1: Number of New Enrollees	DVA E13.1c states that a member is new if s/he disenrolled and reenrolled and an initial HRA was not performed prior to disenrollment. This means that if an initial HRA was performed prior to disenrollment, the member would not be new. This standard conflicts with 06/24/2016 response from CMS (referenced above) where they indicate the following interpretation of the 06/20/2016 Clarification of Data Elements 13.1 and 13.2 communication (refer to Example 1) is correct. CMS's response is the blue text and indicates that plans are to look at each enrollment separately. In the below example, CMS confirmed that a member who received an initial assessment and then disenrolled, reenrolled, and received another initial assessment would in fact be counted as a new member twice. This guidance clearly conflicts with the DVA standards for element 13.1. Example 1: Member enrolls on 2/1/2016, initial HRA completed on 3/15/2016 and member disenrolls 6/1/2016. Same member reenrolls on 8/1/2016 and initial assessment is completed on 10/1/2016 and member remains enrolled through year end. Based on revised guidance, we would count the member and the HRAs twice: 2 under E13.1 and 2 under E13.3. That is correct	N/A	We do not think the DV standards need to be revised, but the guidance from CMS should provide this clarification; per the 7/25/16 updated version of the Part C reporting requirements technical specifications, enrollees who received an initial HRA and remain continously enrolled under a MAO that was part of the consolidation and merger within the same MAO or parent organization will not need to participate in a second initial HRA.

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
Kaiser (kzdr)	E13.1: Number of New Enrollees	DVA E13.1c contradicts DVA E13.1d. As stated above, E13.1c implies a member is not new if an initial HRA was performed prior to disenrollment. DVA E13.1d requires continuous enrollment for an HRA completed in a previous year to indicate the member is not new. This adds a layer of complexity beyond the discrepancies between the DVA standards and the Technical Specifications.	N/A	**Disagree.** It appears that the commentator is assuming that there can be only one condition to match the scenario where a member may be considered a 'new enrollee and eligible for an initial HRA', which is not the case. Further, the two standards are for different scenarios and **do not contradict each other.** RSC 4.d states that members should be excluded from the count of "new members' if they are a continuously enrolled member with an initial HRA in the previous year. This does not contradict with RSC 4.c which states that members should be included as "New members" if initial HRA was not performed prior to disenrollment and subsequent re-enrollment

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
Kaiser (kzdr)	E13.2: Number of Enrollees Eligible for an Annual Reassessment HRA	DVA E13.2d does not include any reference to the 365 day reassessmen t interval. This implies the member is counted as eligible for a reassessment by the close of the measurement year even if day 365 is not reachedthis does not make sense as plans have the full 365 days to complete a reassessment. We raised this same issue with CMS about the technical specifications, April 22 version, and CMS indicated they would issue a clarification. It is critical that the DVA standards are updated to reflect any subsequent clarifications released by CMS.	N/A	**Agree.** It appears that the commentator's contention is that by not explicitly stating the 365-day reassessment interval, it could be interpreted that a member is eligible for reassessment even before the 365 days have passed since the reenrollment, which is incorrect. This is different from the case where an initial assessment was not performed within 90 days of reenrollment (in which case the member becomes eligible for reassessment within 90 days of reenrollment).Includes members who dis-enrolled from and re-enrolled into the same plan if an initial HRA was performed within 90 days of re-enrollment and the member has remained continuously enrolled in the same plan for 365 days since the initial HRA.
Kaiser (kzdr)	E13.3: Number of Initial HRAs Performed on New Enrollees	DVA E13.3b states only HRAs performed between 1/1 and 1 2/31 of the measurement year count which conflicts with the technical specifications which state that if the initial HRA is performed in the 90 days prior to the effective enrollment date, it is included in the reporting year in which the effective enrollment date falls. Refer to the notes section of the technical specifications to see the (the commenter did not finish this sentence)	N/A	We recommend that RSC 7.b be revised to state if the initial HRA occurs before the effective date of enrollment and in a different calendar year, count the initial HRA in the year that the effective date of enrollment occurred.

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
CVS Health (h8g8)	Appendix 1: Data Validation Standards For Data Validation Occurring in 2017	The DV standard appears to limit the reporting of service authorization to pre-services cases only. For example: CMS requires plans to report organization determinations and reconsiderations requests submitted to the plan. For purposes of Reporting Section 6: An organization determination is a plan's response to a request for coverage (payment or provision) of an item or service – including auto-adjudicated claims, prior authorization requests, and requests to continue previously authorized ongoing courses of treatment. It includes requests from both contract and non-contract providers. CMS also states, "In contrast to claims (payment decisions), service authorizations include all service-related decisions, including pre-authorizations, concurrent authorizations and post-authorizations." We encourage CMS to update the documents for consistency between both the DV standards and the Part C reporting technical specifications. Additionally, the DV standards for data element 6.10: Number of Requests for Organization Determinations - Dismissals, reference following the Reconsideration Dismissal Procedure rather than guidance for processing for Organization Determinations - Dismissals.	We encourage CMS to replace the Reconsideration Dismissal Procedure in the Appendix 1 with the guidance for processing for Organization Determinations - Dismissals.	We changed the term "pre-service" with the term "service" in the Data Validation Standards document for the standards for Organization Determinations/Reconsiderations.
Select Health (80c8)	Elements 6.9 and 6.10	In regards to Dismissals and Withdrawls, in one place it says to exclude dismissals, but then in another place it says to include them. (please see elements 6.9 and 6.10)	N/A	CMS will correct this in the Appendix. Dismissals and withdrawals should be included per the technical specifications.

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
Perform Rx (814s)	Consistent Auditor Interpretation (MTM)	PerformRx has experienced a data validation auditor questioning our reporting a cognitive impairment for an enrollee in element H of the MTM Record Layout because we had spoken to the person the year before but had not done a CMR for the current year. There was no citation provided by the data validation auditor for his/her interpretation. The guidance is: 2016 Reporting Requirements: Data Element H. Beneficiary identified as cognitively impaired at time of comprehensive medication review (CMR) offer or delivery of CMR. (Y (yes), N (no), or U (unknown)). Data Validation Standards for Data Validation Occurring in 2016 and proposed for 2017: Organization accurately identifies MTM eligible members who are cognitively impaired at the time of CMR offer or delivery of CMR and uploads it into Gentran, including the following criteria: a. Properly identifies and includes whether each member was cognitively impaired and reports this status as of the date of the CMR offer or delivery of CMR. [Data Element H]	We continue to recommend against using the data validation audit result to validate the CMR completion rate Star Ratings measure until the process is more consistent and more transparent.	CMS disagrees and at this time CMS will continue to use the data validation audit result to validate the CMR completion rate Star Ratings measure. Please feel free to provide any comments regarding the CMR completion rate during the Part D Reporting Requirements 30-day PRA comment period. **CMS Action:** No action taken.

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Perform Rx (814s)	Using Existing MTM Data Validation to Support the Program Audit Process	In recent comments on CMS' 2017 Draft Part D Program Audit Protocols, PerformRx asked CMS to consider removing Table 1 2015 Universe Column IDs A-T from the Part D MTM Program Area PILOT Audit Process and Data Request in Appendix A. This is because CMS collects a similarly detailed MTM report from Part D sponsors annually as part of the Part D Reporting Requirements. The contents of this report are almost identical to the contents of the universe and could be used by the auditors to draw samples. Producing a second report with the same information in a second layout is duplicative.	One option for CMS is to amend its data validation protocols to include a universe validation requirement on the part of the data validation auditors (for the MTM detail report specifically). CMS may find this approach more operationally efficient as well.	This comment is out of scope for the DV PRA.Please submit this comment to the Part D Reporting Requirements and/or MTM mailbox. **CMS Action:** No action taken.

CD/RD for 60-day Comment Period

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
CVS Health (h8g8)	Appendix 1: Data Validation Standards For Data Validation Occurring in 2017	Appendix L – Toolkit for universes for sponsor data validation should be used by the reviewer when validating plan data. The toolkit provides a guide on which data elements to identify from SO data, to validate data submitted in HPMS for this reporting section.	"The document refers to Appendix L, but none of the documents in the attached 2017-2018 DVR Update packet contain Appendix L. We request that CMS please provide information on how to obtain Appendix L. "	Appendix L will be released when the entire DV manual is released. **CMS Action:** No action taken.

Organization	Section	Description of Issue or Question	Commenter's Recommendation	CMS Response/Action
CVS Health (h8g8)	Appendix 1: Data Validation Standards For Data Validation Occurring in 2017	Appendix L includes nine universes listed below: Universe Toolkit 1: Standard Coverage Determinations (U1) Universe Toolkit 2: Standard Coverage Determination Exception Requests (U2) Universe Toolkit 3: Part D Direct Member Reimbursement Request Coverage Determinations (U3) Universe Toolkit 4: Expedited Coverage Determinations (U4) Universe Toolkit 5: Expedited Coverage Determination Exception Request (U5) Universe Toolkit 6: Standard Redeterminations (U6) Universe Toolkit 7: Part D Direct Member Reimbursement Request Redeterminations (U7) Universe Toolkit 8: Expedited Redeterminations (U8) Universe Toolkit 9: Standard & Expedited IRE Auto-forwarded Coverage Determination and Redeterminations (U9)	We request that CMS please: 1) Provide a definition of what Universe Toolkits are, and where they can be located. 2) Provide more information on what will be included in a Universe Toolkit. 3) Provide examples of each Universe Toolkit. 4) Explain how a Universe Toolkit differs from the Primary Source Verification (PSV). For example, would Universe Toolkit 1, which includes Standard Coverage Determinations, have 30 samples as part of the Toolkit, and then another set of samples for the PSV? 5) Provide information regarding when these universes should be provided to the Data Validation reviewer. 6) Provide details regarding who should provide the universes to the Data Validation reviewer.	CMS developed Appendix L's Universe Toolkit using the universes collected for CMS' program audit of sponsors' Part D Coverage Determinations, Appeals, and Grievances processes. This toolkit will correlate directly with the Findings Data Collection Form and should be used by the reviewer as a reference to validate plans' reported data for the Coverage Determinations and Redeterminations Reporting Section. Appendix L is a resource document, used for data validation purposes only. CMS does not intend to collect universes through HPMS. Appendix L will be released with the final DV manual. Questions and comments should be sent via email to: PartCandD_Data_Validation@cms.hhs.gov. **CMS Action:** No action taken.
MMMHC (85e4)	Appendix 1: Data Validation Standards For Data Validation Occurring in 2017	We noticed that the Data Elements on page 33 (3.B.13.B.10) for the reopening section are not aligned with the above list. Please clarify.	N/A	CMS will revise the Data Elements on page 33. **CMS Action:** CMS revised the Data Elements on page 33.

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MMMHC (85e4	Appendix 1: Data Validation Standards For Data Validation Occurring in 2017	The questions regarding the high cost edits for compounds were eliminated for the 2017 Reporting Requirements; however, we noticed that the 2017 Data Validation Standards includes elements regarding high cost edits for compounds. Please clarify, if high cost edits for compounds will be a measure for contract year 2017. Will 2017 Reporting Requirements be updated to include high cost edits for compounds?	N/A	The high cost edits for compounds was removed for 2017 reporting but will remain in 2016 reporting therefore, it is properly listed in the 2017 DV. The high cost edits for compounds will be removed from 2018 DV. **CMS Action:** No action taken.
United Healthcare (tc7y)		The DV standards appear to limit the reporting reason(s) for reopening to Clerical Error, New and Material Evidence, or Other. We respectfully ask CMS to clarify whether Fraud and Similar Fault will continue to be a reason for reopening in the 2016 measurement period.	We encourage CMS to update the DV standards to include Fraud and Similar Fault, which aligns with Chapter 13 and the reopening reporting template.	CMS agrees and will revise the DV standards to include Fraud and Similar Fault, which aligns with Chapter 13 and the reopening reporting template. **CMS Action:** CMS revised the DV Standards to include Fraud and Similar Fault.