

9/9/2014

**Responses to Comments Received Federal Register Notice on Revised  
CMS-10305 (0938-1115):  
Medicare Part C and Part D Data Validation**

CMS received three (3) public comment submissions on the June 13, 2014 notice on the proposed changes to The Medicare Part C and Part D Data Validation (CMS-10305). The commenters were: ClearStone Solutions, UnitedHealthcare, and AHIP. In addition, CMS also received two comment submissions from its dedicated email address for the Part C and Part D Data Validation. These comments were from data validation contractors: ATTAC Consulting Group and HDC Data. There were also three comment submissions from the email address dedicated to Part D Reporting. These comments were from Healthcare Data Company (data validation contractor) and Blue Cross Blue Shield Northern Plains Alliance. Finally, based on “lessons learned” through the 508 compliance process, CMS made changes to the “Findings Data Collection Form.”

**General Comment on CMS-10305**

The supporting documents for CMS-10305 have never been made available.

**CMS Response**

CMS made the supporting documents available at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10305.html?DLPage=1&DLFilter=CMS-10305&DLSort=1&DLSortDir=descending>

**CMS Required Data Validation Reporting**

Data Validation (DV) reports that are provided to the Centers of Medicare & Medicaid Services (CMS) by each Sponsor Organization (SO) summarize pharmacy claim data that is duplicative information already provided to the CMS through Prescription Drug Event (PDE) submissions. Having each SO produce, maintain, and enhance these reports adds unnecessary expense to the healthcare system; as stated in this CMS release, in total over \$15 million and an additional \$300 thousand to the government for monitoring. The preference is for these dollars be used to offer Medicare beneficiaries either lower cost-sharing or increased benefits instead of inefficiencies in reporting. We recommend CMS evaluate the reports currently being provided to determine those that are duplicative summaries of data available through PDE submissions. Where this is taking place, the recommendation is that the CMS use one consistent application to summarize the results instead of requesting these summaries from each SO.

**CMS Response**

This commenter did not specify the reporting section; however, CMS believes this commenter is referring to the LTC Utilization reporting section. CMS is currently exploring using PDE data to analyze LTC utilization. We will provide additional information for the 2016 Part D Reporting Requirements PRA.

### **Inconsistency between Reporting Section Criteria (RSC) with Data Element 6.1 of the Part C Technical Specifications**

RSC for Data Element 6.1 indicates that the organization should accurately calculate the number of *fully favorable* organization determinations. The phrase “fully favorable” appears inconsistent with Data Element 6.1 of the Part C Technical Specifications, which requires the reporting of the “total number of organization determinations made in [the applicable] reporting time period.”

#### **CMS Response**

CMS has reviewed and revised the language in the Standards to conform to the Data Element 6.1 language in the Part C Technical Specifications.

#### **Alignment of Terminology**

CMS replaced the term “measure” with “reporting section” and the term “measure-specific criteria” with “reporting section criteria.” There are several places in Appendix 1 where the terminology has not been revised.

#### **CMS Response**

CMS has reviewed the data validation documents and revised the terminology accordingly.

### **Inconsistency between the Standards and the Part D Technical Specifications (Note 14, page 62)**

Item #13 under the RSC of Section 2.7 for Appendix 1 indicates that for data Element 1.N the organization accurately calculates “the number of coverage determinations decisions processed timely.” However, Note 14 in the corresponding Part D Technical Specifications states that certain untimely cases should also be included in Data Element 1.N (refer to Note 14, page 62). Note 14 appears to conflict with the Data Validation Standard described in Item #13.

#### **CMS Response**

CMS has updated the 2014 Part D Technical Specifications to clarify Note 14 for the Coverage Determinations and Redeterminations reporting section. Untimely cases should not be included in Data Element 1.N.

#### **Reporting of Expedited Grievances**

Sponsors should report expedited grievances in 2 elements: the total number of expedited grievances, as well as in the appropriate grievance category. For example, if an enrollee files an expedited grievance because the plan denied their request for an expedited coverage determination, that grievance should be reported both as an “Expedited Grievance” and also as a “Coverage Determination and Redetermination Process” grievance.

## **CMS Response**

This may be considered for the future. Currently, this would involve additional reporting burden which we think outweighs the potential benefits of this information at this time.

## **Threshold for Individual Part C and Part D Grievance Categories**

This commenter recommends applying the 90% threshold to the individual grievance categories (eliminating the need for 100% correct categorization of the individual grievance categories). The current requirement is not consistent with the 90% threshold applied to all other data validation standards and other aspects of Part C/D grievances data validation. In addition, application of correct categorization of individual grievance categories (at the 100% threshold) unfairly penalizes plan sponsors for “one-off” type errors that would otherwise fair well under the data validation standards for this measure.

This commenter also recommends providing clarity around correct grievance categorization (i.e. clear category definitions and examples), consistency between Part C and Part D notes to reviewer within the data validation standards, and the application of the threshold.

## **CMS Response:**

CMS does not agree that the 100% threshold should be changed to 90% for the individual grievance categories. A contract could “miss” on every category, yet meet the 90% threshold. The latest data validation results indicated mean data validation scores of 98.0% and 98.3% Part C and Part D Grievances Reporting Sections, consecutively. This result demonstrates that the majority of contracts were able to meet the 100% standard.

The second comment is perhaps more relevant to the Part C and Part D Reporting Requirements Information Collection Requests (ICRs). However, it is a valid comment and CMS will add examples for the grievance categories in the next editions of the Technical Specifications.

## **Additional Clarity regarding Oral Grievances**

This commenter recommends providing plan sponsors additional clarity regarding the inclusion of oral grievances received / identified and resolved at the point of contact (i.e. in a Customer / Member Service unit) in plan grievance reporting. In this commenter’s experience, numerous plan sponsors are identified that are not clear on this matter and/or are not appropriately counting oral grievances received by their Customer / Member Service unit and resolved at the point of contact. Additional clarification (and examples) regarding these oral grievances and their inclusion in plan sponsor reporting in the Part C and Part D manual chapters, reporting requirements / technical specifications, and data validation standards would be helpful.

**CMS Response:**

This comment is perhaps more relevant to the Part C and Part D Reporting Requirements Information Collection Requests (ICRs). However, it is a valid comment and CMS expects all grievances, regardless if submitted in writing or orally, will be reported. We will add clarification in future Reporting Requirements documents.

**Use of Separate/Independent Measures in the Data Validation of Part C Organization Determinations and Reconsiderations and Part D Coverage Determinations and Redeterminations**

This commenter recommends that Part C Organization Determinations and Reconsiderations and Part D Coverage Determinations and Redeterminations be addressed as separate / independent measures within the data validation standards. Due to the nature of the underlying business processes and reporting requirements, most often, Organization Determinations and Reconsiderations are handled using separate systems, processes, and personnel.

**CMS Response:**

We disagree that Part C Organization Determinations and Reconsiderations and Part D Coverage Determinations and Redeterminations should be separated. CMS' experience with Part C and D Sponsors' processing of coverage determinations, organization determinations, and redeterminations has shown these activities are often managed and processed in a comprehensive manner – that is, the responsibilities, and workflow fall under the same areas of the organization. CMS also believes separating these sections may add to the complexity of the data validation process as well as introduce inconsistency in scoring since the same DVAs would be unlikely to be involved in the two separate parts of the data validation, yet the underlying processes by the Sponsor are related.

**Inclusion of Additional Code for Part D Long-term Care Utilization**

This commenter recommends the addition of patient residence code 09 be included as an allowable value in the Part D technical specifications and data validation standards.

**CMS Response:**

CMS is currently exploring using PDE data to analyze LTC utilization. We will provide additional information for the Part D Reporting Requirements Information Collection Requests (ICRs). At this time, CMS does not approve any methodologies used by Plan Sponsors to generate reports. Plan Sponsors have discretion in identifying LTC and Retail claims/utilization using any patient residence codes they deem necessary to complete the elements in the LTC Utilization report. CMS expects Plan Sponsors to present upon request all rationale and documentation for their designations.

## **Guidance for Medication Therapy Management Program Reporting Section**

This commenter recommends that CMS provide additional guidance regarding what constitutes acceptable interpretation of cognitive impairment for the purposes of plan reporting requirements and data validation.

CMS Response:

The Cognitive Impairment data element (Data Element H) is intended to identify if a beneficiary is deemed to be cognitively impaired for purposes of participation in their CMR. CMS agrees that cognitive status can vary on any given day but do not have a mechanism for Plan Sponsors to report intermittent cognitive impairment that may affect a beneficiary's ability to participate in some but not all of their CMRs. CMS expects Plan sponsors to select 'Y' for Element H if the beneficiary was determined to be cognitively impaired at the time of the offer or delivery of any of their CMRs in the reporting period. CMS expects Plan Sponsors to present upon request all rationale and documentation for their designations.

## **Table of Contents for Data Validation Standards**

This commenter noted that the table of contents in the Data Validation Standards document does not align with the section numbers noted throughout the document.

CMS Response:

CMS will make the necessary alignment of the section numbers in the Data Validation Standards document.

## **Identifying Changes and/or Updates to the Data Validation Standards Document**

This commenter recommends providing additional clarity to identify changes and/or updates (i.e. redline versions) to the data validation standards document and related materials for ease of review and comment.

CMS Response:

The 508 compliance requirements do not allow for redline documents.

## **Inclusion of the Data Validation Procedure Manual in Documents for Comment**

This commenter noted that the Data Validation Procedure Manual was not included in the documents for comment. The Data Validation Procedure Manual appears to require revision based upon the changes to reporting measures undergoing validation.

**CMS Response:**

The Data Validation Procedure Manual will be revised in accordance with the changes made in the other documents contained in this ICR.

**CMS Response:**

This comment is perhaps more relevant to the Part C and Part D Reporting Requirements Information Collection Requests (ICRs). However, it is a valid comment and CMS will add examples for the grievance categories in the next editions of the Technical Specifications.

**Findings Data Collection Form (FDCF) Changes Needed—CMS “Lessons Learned”**

Due to its experience with achieving FDCF 508 compliance, CMS benefitted from “lessons learned.” CMS believes that improvements in the FDCF are needed to make it more “user-friendly” and to serve as a more effective “blueprint” for reporting data validation results in the Health Plan Management System (HPMS). CMS had difficulty with the excel format for the form and switched to a word format. In addition, the old form, which was used as the main model for recording data validation data in HPMS, did not allow DVAs to record separate findings for many single data elements. Previously, the findings pertained to aggregates of data elements that were not as effective in informing sponsors of specific problems with individual data elements.

**CMS Response to Its Own Recommendation**

CMS has revised the FDCF. The revised FDCF is a substantial improvement in that findings will be recorded for the majority of individual data elements.

**Grievances Reporting**

We do not see any mention in the DV Standards V.5 (PRA) requiring D and E to be subsets of P and Q. Is CMS asking that Expedited Grievances related to refusal to Expedite a Coverage Determination be reported both at D/E and that the D/E figures be added to P/Q?

Is CMS asking that Expedited Grievances related to refusal to Expedite a Redetermination be reported at both D/E and that the D/E figures be added to some other category pair? Which pair?

CMS Response:

CMS expects Plan Sponsors to report Expedited Grievances related to refusal to expedite a coverage determination as both an expedited grievance and as a Coverage Determinations and Redeterminations grievance.

### **Plan Oversight of Agents Discrepancies**

There seems to be some discrepancies between the Medicare Part D Reporting Requirements, the Data Validation Standards and the Medicare Part C Reporting requirements as it pertains to which agents should be included in the reporting.

NPA's assumption is that they should only report agents who earned and received compensation for members with an effective date of 1/1/2014-12/31/2014. Therefore, if an agent earned compensation in 2013 but did not receive payment until early 2014, they would be excluded (assuming they had no other new enrollments with a 2014 effective date). Similarly, if an agent earned compensation in 2014 but did not receive payment until early 2015, they would also be excluded.

CMS Response:

CMS expects Plan Sponsors should report agents/brokers that have earned and received compensation during the reporting period.

### **Coverage Determinations and Redeterminations Reporting of Dismissals and Withdrawals**

For data element 2.A, the Technical Specifications and DV Standard 16i are inconsistent with DV Standard 19c. Data Element 2.A and DV Standard and 16i state that dismissals and withdrawals should not be included in Data Element 2.A; however, DV Standard 19c states that they should be included. Are the Technical Specifications and DV Standard RSC 16i correct in that dismissals and withdrawals are not included in element 2.A?

CMS Response:

Yes, the Technical Specifications and RSC 16i are correct in that dismissals and withdrawals are not included in element 2.A. RSC 19c will be revised to state: Each number calculated requests for redeterminations that were withdrawn (Data Element 2.F) and requests for redeterminations that were dismissed (Data Element 2.G) is not included in the number of redeterminations decisions made (Data Element 2.A).