

ATTAC Consulting Group, LLC
OMB Comments on Paperwork Reduction Act Package 10305
Data Validation Auditing Standards

The following represents ATTAC Consulting Group, LLC's (ACG) comments on the Paperwork Reduction Act Package 10305, developed by the Centers for Medicare and Medicaid Services (CMS) to obtain the Office of Management and Budget's approval to implement Part C and Part D Data Validation Requirements in 2011 based on 2010 data.

CMS has worked through a contractor to develop Part C and Part D Data Validation requirements. CMS' stated goal for DVA is to test plan quarterly and annual reported data to assure that it receives "Reliable, Valid, Complete and Comparable data from the Medicare Advantage Organizations (MAO) and Prescription Drug Plans (PDP). The data is needed "in order to respond to Congress, oversight agencies, and the public about costs, availability of services, beneficiary use of available services, public safety, grievance rates, and other factors that pertain to MAOs and PDPs." CMS will also use the data to oversee and monitor MAOs and PDPS and to conduct the compliance and auditing activities necessary to ensure that Medicare beneficiaries receive the Part C and D benefits that CMS has contracted for on their behalf.

ACG is a nationally recognized auditing and consulting firm. It has extensive experience with assisting MAOs and PDPs maintain compliance with the regulations that underlie the data validation requirements. In addition, ACG has already begun performing preliminary data validation for both MAOs and PDPs, helping them identify deficiencies in data collection methods and guiding the corrective action that will resolve the deficiencies and allow Part C and D data to be efficiently validated during the 2011 audit period.

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.

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.

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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 respectfully submit that making the clarifications suggested below will enhance MAO and PDP reporting accuracy and allow for expedited data validation.

I. Global Comment on Data Validation Requirements

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.

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.

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.

ACG recommends the following standard:

1. 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.
2. 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

II. Comments on Measure-Specific Criteria in the Data Validation Requirements

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.

PART C Measure 2.1: Benefit Utilization

Regarding Measure-Specific Criteria 6-9

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.

Part C Measure 2.3: Serious Reportable Adverse Events

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.

Part C Measure 2.4: Provider Network Adequacy

Regarding Measure-Specific Criteria 4-6

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.

- a. 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.
- b. 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.
- c. 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.)

Regarding Measure-Specific Criteria 5 & 11

ACG recommends further definition be developed for the purpose of testing “continuously” part of the network.

- a. That providers be contracted on Day 1 and Day 365 without a lapse in availability of service provided
- b. That if a provider’s contract has expired, but been extended during negotiations, that provider also be counted.
- c. 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.

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Regarding Measure-Specific Criteria 7

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.

Regarding Measure-Specific Criteria 10-12

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?

Part C Measure 2.5: Grievances

Regarding Validation Standard 2 and Measure-Specific Criteria 5

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.

**Part C Measure 2.6: Organization
Determinations/Reconsiderations**

Regarding Measure-Specific Criteria 5

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.

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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.

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.

Part C Measure 2.8: Plan Oversight of Agents (Part C)

Regarding Measure-Specific Criteria 2

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.

Regarding Measure Specific Criteria 4

Some states do 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”

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Regarding Measure Specific Criteria 5

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.

Regarding Measure Specific Criteria 8

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.)

Part D Measure3.2: Medication Therapy Management Programs

Regarding Measure Specific Criteria 5-6

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)

Part D Measure 3.3: Grievances

Regarding Measure-Specific Criteria 5

See Part C Grievances Measure-Specific Criteria 5 above.

Regarding Measure-Specific Criteria 7

Low Income Subsidy (LIS) status changes frequently and will impact whether MA-PD 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 be reported by the MA-PD or PDP, i.e. as an LIS member or not.

Part D Measure 3.4 Coverage Determinations

Regarding Measure-Specific Criteria 5

“Pharmacy Transactions” should be better defined. Does it include or not include EA drugs transactions?

III. Comment on Sampling Instructions

- a. Sample Sizes to not appear to be appropriately stratified for smaller plans.
- b. 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.