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TO: All Medicare Advantage Organizations, Part D Sponsors, 1876 Cost Plans, and Potential Third-Party Data Validation Contractors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Clarification of Policy Regarding Independence of Data Validation Contractors

DATE: February 17, 2012

This memorandum serves to clarify our policy regarding the responsibility of sponsoring organizations to ensure that their selected data validation contractors (and subcontractor(s), if applicable) meet the standards for organizational independence as described in Version 2.0 of the Data Validation Procedure Manual and Appendix A: Standards for Selecting a Data Validation Contractor.

We have recently received questions regarding these standards, particularly about the Version 2.0 instruction that data validation contractors may perform mock audits, pre-assessments, and any other types of review only during the formal data validation review period between April 1 and June 30. We therefore are clarifying this instruction and its applicability to the upcoming 2012 data validation cycle.

As stated in Appendix A: Standards for Selecting a Data Validation Contractor, consultants who provide management consulting or assist the sponsoring organization with its reporting procedures, reporting processes, or information systems used in storing, compiling, or reporting the Part C and/or Part D Reporting Requirements data to CMS may not serve as the data validation contractor for that organization. CMS believes these types of activities that take place prior to the sponsoring organization's initial Part C and/or Part D Reporting Requirements data submission or that cause the sponsoring organization to resubmit data prior to the March 31 resubmission deadline create a relationship that does not meet CMS' standard for organizational independence in conducting the data validation review.

However, we recognize that many sponsoring organizations may have already had contractual relationships in place with data validation contractors prior to the January 24, 2012 release of the Version 2.0 instructions, and that the scope of work included in those contracts may include the performance of mock audits, pre-assessments, and other types of review prior to the April 1 beginning of the 2012 data validation review cycle. CMS will allow this work to continue provided the sponsoring organization can demonstrate (if requested) that the contract was

executed and work began prior to January 24, 2012. However, in the future, this will not be allowed (refer again to Appendix A: Standards for Selecting a Data Validation Contractor).

The following “Frequently Asked Questions” provide additional clarification around this instruction.

Q: What is the definition of a “mock audit” or a “pre-assessment?”

A: CMS uses both of these terms to refer to any activity to assist the sponsoring organization with its reporting procedures, reporting processes, or information systems used in storing, compiling, or reporting the Part C and/or Part D Reporting Requirements data to CMS and/or to assess the organization’s performance and make improvements to its internal data, systems, and reporting processes.

Q: Are sponsoring organizations prohibited from using contractors to conduct mock audits, pre-assessments, and other types of review?

A: No. The Version 2.0 Data Validation Procedure Manual instruction does not prohibit the use of contractors to conduct mock audits, pre-assessments, and other types of review during the compilation and reporting and/or resubmission of required data prior to the April 1 beginning of the data validation cycle. These types of activities contribute to CMS’ goal of ensuring that Part C and Part D organizations are reporting health and drug plan data that are reliable, valid, complete, comparable, and timely. However, in order to meet CMS’ standards for organizational independence, a sponsoring organization may not use the same contractor to conduct the subsequent validation of those reported data.

Q: When can the sponsoring organization share the completed Organizational Assessment Instrument (OAI) with its selected data validation contractor?

A: A sponsoring organization may send the completed OAI, along with the documents and files requested in Section 5 of the OAI (e.g., source code, process flows, standard operating procedures, etc.), to its selected data validation contractor prior to the April 1 start of the data validation cycle; however, the data validation contractor should be using this documentation to help prepare for data validation and should not be assisting the sponsoring organization with data corrections and/or data resubmissions.

Q: Can data validation contractors share their data validation findings with their client sponsoring organizations and make recommendations for how to correct deficiencies for future reporting?

A: Yes. Data validation contractors must share their draft data validation findings with the organization and must resolve any issues identified prior to the June 30 deadline for submitting final findings to CMS. However, because this activity takes place after the April 1 start of the data validation cycle, sponsoring organizations may not resubmit data to CMS in order to change any draft data validation findings that identified errors in the data submitted. CMS also

encourages data validation contractors to make recommendations to their client sponsoring organizations for how to correct any identified deficiencies and/or address potential weaknesses in the organization's internal data, systems, and reporting processes for the future. Recommendations that are a direct result of the data validation findings and are provided to the sponsoring organization prior to the June 30 deadline for current year's data validation cycle will not cause the data validation contractor to violate CMS' standard for organizational independence in conducting the following year's data validation review for the same sponsoring organization.

Q: My data validation contractor for the upcoming 2012 data validation cycle started working in September 2011 and has identified reporting errors that my organization has already addressed by resubmitting data? Is this acceptable to CMS?

A: Yes, for the upcoming 2012 data validation cycle only, CMS will allow this work to continue this year provided the sponsoring organization can demonstrate that the contract was executed and work began prior to January 24, 2012.

Q: My data validation contractor for the upcoming 2012 data validation cycle started working in January 2012 and has identified data reporting errors that my organization plans to address by resubmitting data prior to the March 31 resubmission deadline? Is this acceptable to CMS?

A: Yes. For the upcoming 2012 data validation cycle only, CMS will allow this work to continue provided the sponsoring organization can demonstrate that the contract was executed and work began prior to January 24, 2012.

Q: My data validation contractor for the upcoming 2012 data validation cycle is scheduled to start working in February or March 2012.

- 1. Can this contractor review and correct errors in any data that my organization has not yet submitted to CMS?**
- 2. Can this contractor review the data that my organization has already submitted to CMS and, if errors are identified, can my organization resubmit corrected data prior to the March 31 resubmission deadline?**
- 3. Is this acceptable to CMS?**

A: The answer is no for all three questions. Because this work is scheduled to begin after January 24, 2012, these activities would cause the data validation contractor to not meet CMS' standards for organizational independence.

CMS believes the data validation contractor's independence is a critical element in ensuring Part C and D data are accurate, consistently reported, reliable, and valid, and will be developing further guidance for the 2013 data validation cycle to ensure there is a clear distinction between data reporting and data validation.

If you have additional specific questions regarding the data validation program, please direct them to CMS via the PartCandD_Data_Validation@cms.hhs.gov email box.

Thank you.