

**COMMENTS OF KAISER PERMANENTE ON
DATA VALIDATION MATERIALS IN APRIL 19, 2010 PRA NOTICE
CMS - 10305/OMB#0938-NEW**

Kaiser Foundation Health Plan, Inc. and its subsidiary Kaiser Foundation Health Plans (collectively "Kaiser") contract with CMS as Medicare Advantage Organizations (MAOs) and Medicare Cost contractors sponsoring Part D benefits. Kaiser is thus subject to both the Part C and Part D Reporting Requirements promulgated by CMS, and the data validation audit requirements established by rule published in the Federal Register on April 15, 2010. Kaiser appreciates this opportunity to comment on the documents released by CMS and published in a PRA notice in the Federal Register on April 19, 2010. Because the "Supporting Statement for PRA Submissions: Medicare Part C and Part D Data Validation" ("Supporting Statement"), published on March 10, 2010, is integrally related to the PRA documents, Kaiser will comment on it as well.

Supporting Statement

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.

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.

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.

Organizational Assessment Instrument (Appendix 2)

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.

Instructions for 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.

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.

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.

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.

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."

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.

Sampling Instructions for Data Validation Contractors

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.

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".

If CMS personnel have questions about these Comments or seek further information, please contact Daren Pursche (Daren.Pursche@kp.org, 510 271-5880) or Judith Mears (Judith.Mears@kp.org, 510 271-5964). Thank You.