COMMENTS OF KAISER PERMANENTE ON
CMS' PAPERWORK REDUCTION ACT SUBMISSIONS
FOR CHRONIC CARE IMPROVEMENT PROGRAM AND
MEDICARE ADVANTAGE QUALITY IMPROVEMENT PROJECT
CMS - 10209 (OMB 0938-1023)
August 16, 2010

Kaiser Foundation Health Plan, Inc. and some of its subsidiary Kaiser Foundation Health Plans (collectively "Kaiser") contract with CMS as Medicare Advantage Organizations ("MAOs"), serving approximately 800,000 beneficiaries who are Kaiser members. Kaiser is thus subject to CMS requirements governing both Quality Improvement Projects ("QIPs") and Chronic Care Improvement Programs ("CCIPs"). Kaiser appreciates the opportunity to comment on the PRA Submissions that were published in the July 2, 2010 Federal Register, as these documents ("Documents"), especially the Supporting Statement and the two Reporting Templates, evidence CMS' intention to make significant changes in its requirements with respect to QIPs and CCIPs.

CMS intends to require MAOs to submit to a CMS vendor, on an annual basis, a new QIP and a one-year report about progress in its ongoing CCIP. This is a new and significant burden.

Currently MAOs submit their QIPs and CCIPs in advance of biennial CMS audits/site visits, when the QIPs and CCIPs are typically reviewed by the RO CMS staff who are conducting the visit. If the MAO has engaged with NCQA to earn "deemed" status for its QIP and/or CCIP, CMS staff typically note the "deemed" status and do not themselves review the QIP/CCIP.

CMS' requirement that every MAO must annually submit a new QIP and a one-year progress report on its ongoing CCIP for (a) review and scoring by its vendor (Optimal Solutions Group, LLC, "Optimal"), and (b) possible Corrective Action Plan ("CAP") imposition by CMS, is a significant change and a significant burden. There is no explanation as to why this change to an annual submission schedule is necessary. Considering that CMS audits the financial solvency of MAOs every three years, and conducts MAO site visits biennially, and the subject matter of those reviews are more critical to the foundational compliance of MAOs than QIPs and CCIPs, we believe that CMS should adopt a similar biennial or triennial submission schedule for these QIPs and CCIPs. Such a schedule would enable Optimal to review more intensively and score a smaller number of QIPs and CCIPs, would allow CMS to focus more fully on any "problem" QIPs and CCIPs flagged by Optimal's "scoring", and would allow CMS to apply the results of one year's experience to the following year's reviews, while reducing the burden on MAOs. (On this same point, we believe that CMS has seriously underestimated the time required for Optimal to conduct reviews of every MAO's QIPs and CCIPs. Optimal is now being charged to do much more work than the three or four MAQROs which previously served all of the United States, but which only reviewed QIPs biennially and not at all for "deemed" plans.)

The QIP and CCIP reporting templates are in disarray.

Over the last three years, CMS has published different versions of the QIP and CCIP reporting templates at different times and in different ways (guidance memorandum, on its website, etc). CMS' vendor, Optimal, has also published QIP and CCIP reporting templates on its website. CMS' most recent operational instructions to MAOs, by way of its July 9, 2010 and July 23, 2010 memoranda, is that they should use the reporting templates on the Optimal website for the submission of their QIPs and CCIPs to Optimal by August 27, 2010, However, the reporting templates on the Optimal website are not the same as either (1) the OMB-approved templates that CMS has published in the past, or (2) the templates included in the Documents included in this PRA notice. It appears, therefore, that MAOs have been instructed to use a reporting

template that is not OMB-approved. CMS must address this problem in the near term (with respect to the submissions due August 27, 2010), and in the longer term (a new PRA notice if CMS intends to adopt and require use of the templates on the Optimal website.)

CMS' intention to require annual submission of QIPs and CCIPs to its vendor Optimal ignores the NCQA "deeming" process, and subjects "deemed" MAOs to duplicative reporting.

MA regulations (42 CFR 422.152) and Medicare Managed Care Manual Chapter 5 explicitly authorize MAOs to satisfy QIP and CCIP requirements by satisfying the accrediting standards of CMS-approved organizations such as NCQA. Such "deemed" MAOs satisfy standards that are enforced by NCQA, but agreed upon by NCQA and CMS. Some of the Kaiser MAOs have "deemed" status, and have invested significant time, money and effort in acquiring and maintaining such status.

CMS' Documents do not mention NCQA or "deemed" status at all. There is no exception from CMS' annual reporting for MAOs whose QIPs and CCIPs are "deemed". (In a July 23, 2010 memo governing the QIP and CCIP reports that CMS has required to be submitted this month, CMS clarifies that MAOs with "deemed" plans are not exempt from reporting. We assume that is also CMS' position with respect to the annual reporting described in these Documents). It appears therefore, that CMS contemplates separate, different and parallel reporting by MAOs to both NCQA and CMS, using different Reporting Templates, and separate, different and parallel review by both CMS and NCQA. The result is expensive and time-consuming application of resources and duplication of efforts by MAOs. Does CMS intend to remove QIPs and CCIPs from the scope of review of the biennial site visit? If so (and it would seem so, given the implication of centralized review in these Documents), then "deemed" status, with respect to QIPs and CCIPs, would seem to have no residual value at all.

Because the Documents do not exempt "deemed" QIPs and CCIPs from the annual Optimal review, nor give "deemed" QIPs and CCIPs any preference or advantage in that review process, it is entirely possible that a "deemed" QIP/CCIP could be scored poorly by Optimal and become subject to a CMS-imposed CAP. At that point, surely "deemed" status for QIPs and CCIPs is value-less, and the MA regulation (42 CFR 422.152) and Medicare Managed Care Manual Chapter 5 acknowledging "deemed" status are meaningless. Is this the outcome CMS intentionally seeks?

At the very least, CMS should coordinate its efforts with NCQA so that the QIP/CCIP Reporting Templates of both organizations are the same. This would reduce the burden on MAOs without impairing either organization's prerogatives. But we also strongly believe that CMS should take a further step by either (a) exempting "deemed" QIPs and CCIPs from its annual submission process altogether, or (b) placing "deemed" QIPs and CCIPs on a biennial or triennial submission timetable, while non-"deemed" QIPs and CCIPs would be submitted annually.

CMS has not disclosed or described the standards to be used by CMS' vendor Optimal in conducting review and scoring QIPs and CCIPs.

The Documents do not disclose or describe the standards that Optimal will use to conduct the review and scoring of QIPs and CCIPs. The Documents refer to "predetermined criteria" but provide no further information. It is imperative that MAOs have at least a general idea of the standards that will be used to score their plans, especially when failure to meet those standards will result in a CAP. In contrast, NCQA tells MAOs that seek to have their QIPs and CCIPs "deemed" what standards NCQA will use to review their QIPs and CCIPs, and how NCQA will score QIPs and CCIPs, based on these standards.

CMS has previously spoken about conflicts between its own standards for QIPs and CCIPs, and the standards of accreditation organizations such as NCQA, and promised that the latter would prevail. In its comments about its new authority to mandated specific QIPs and CCIPs, in a final rule published in the Federal register on April 15, 2010, there is this colloquy:

> "*Comment:* Several commenters were concerned that the proposed requirements could impinge on the efforts of MAOs to satisfy accreditation standards for NCQA or other accrediting bodies.
> *Response*: MAOs that participate in the quality improvement deeming program will be subject to the standards of their accreditation organization. We will continue to ensure that standards applied by deeming organizations are at least as stringent as those applied by us." (75 FR 19757)

We know NCQA's standards for reviewing QIPs and CCIPs, but CMS has not disclosed its own standards. Moreover, CMS has not said (and should say, in fulfillment of its foregoing promise in the Federal Register) that a QIP or CCIP that meets NCQA's standards will automatically meet CMS' standards, whatever they turn out to be. In light of CMS' commitment to "transparency", and to making performance data on MAOs available to multiple audiences, CMS should also be "transparent" with respect to the standards its vendor Optimal will use for these reviews. Otherwise, the review and the scoring become a "black box" experience, from which no MAO learns but all may suffer reputational and regulatory damage.

The review and scoring of a QIP or CCIP by CMS' vendor Optimal could result in a CAP.

The Documents say that CMS will enter "audit findings" based on Optimal's review and scoring, and will require a CAP if warranted. There is no discussion or description about how or when Optimal's scoring will lead to a CMS determination that a CAP is required. CMS refers vaguely to "outliers and data abnomalities", but because the Documents contain no review criteria or scoring information, there is no way to know what this phrase means. Because any CAP has significant negative implications (including public dissemination and potential impact upon an MAO's star rating), MAOs should be told clearly what they must do to avoid a CAP for their QIP and/or CCIP. The Documents do not do this.

As a result of CMS' unwelcome silence in this regard, it is impossible to tell if CMS intends to use CAPs to target (a) QIPs/CCIPs that are poorly designed, or (b) well-designed QIPs/CCIPs that are poorly implemented, or (c) well-designed and well-implemented QIPs/CCIPs that are not showing progress made on quality indicators. Or all three. Or perhaps CMS will impose a CAP on a QIP or CCIP that an MAO is using for its commercial membership and for its MA membership at the same time. (CMS has not said whether it will score such a QIP or CCIP lower, but the inference is that CMS want to see Medicare-specific QIPs and CCIPs. This is just one of the review/scoring elements that CMS should clarify.)

Some MAOs, especially smaller ones, would welcome expert assistance in the development of a QIP and/or CCIP. The Documents say that Optimal will be available for technical assistance during the CAP process. But it's not clear if Optimal or the MAQROs will be available to provide technical assistance during the development of a new QIP or CCIP, so that deficiencies could be "fixed" there.

When will CMS require an MAO to adopt a particular QIP and/or CCIP?

It is noteworthy that the Documents do not mention the new authority that CMS has to dictate to an MAO that it adopt a particular QIP and/or CCIP. This curious silence leaves MAOs to guess whether, when and how CMS intends to use this new authority in conjunction with its annual submission requirement. In the final rule published in the April 15, 2010 Federal Register,

CMS stated its belief that "giving MAOs complete discretion to establish their own CCIPs and QIPs does not allow beneficiaries to effectively compare plans and organizations to manage and report projects." CMS also stated its belief that "these projects are not addressing quality improvement areas that we believe best reflects beneficiary needs." CMS noted that in the proposed rule it had said that it would "annually inform MAOs individually and/or generally which patient populations and areas we have determined would benefit most from a CCIP and QIP." In the final rule CMS noted that "many commenters opposed our proposals" but finalized the proposed rule without any substantive changes, stating:
"...we will annually inform MAOs individually and/or generally of the process by which CCIPs and QIPs must be conducted, which tools to use to report activities, and the timeframe for submitting data and reports. We will also use these communication methods to identify the patient populations and areas we have determined would benefit most from CCIPs and QIPs. However, as noted previously, this does not preclude MAOs from developing CCIPs and QIPs that they independently determine to be needed for their population". (75 FR 19755-19757). A conservative interpretation of this text is that an MAO may conduct more QIPs and CCIPs in addition to the ones "assigned" to it by CMS!

The Documents, however, do not mention this new authority or whether/how CMS will exercise this authority in conjunction with the annual review of QIPs and CCIPs submitted by MAOs. Will only MAOs whose QIPs and CCIPs "fail" Optimal's scoring and/or give rise to a CAP be subject to a CMS-mandated QIP/CCIP? If CMS decides to mandate a particular QIP or CCIP for an MAO, will it notify that MAO before, after or during the MAO's submission of its current QIP/CCIP? Will CMS set aside "deemed" QIPs and CCIPs to mandate projects of its own choosing? MAOs need and deserve the guidance that CMS said it would give them about the exercise of this new authority, and how it relates to the annual reporting requirement that CMS is describing in these Documents.

Conclusion

In conclusion, Kaiser strongly urges CMS to adopt a collaborative, rather than prescriptive, approach to improving QIPs and CCIPs. At the very least, CMS should host an industry-wide Open House to exchange information, policy viewpoints and best practices before it finalizes its annual reporting requirements and the report templates to be used therein. If CMS personnel have questions about these Comments or seek further information, please contact Judith Mears (Judith.Mears@kp.org, 510 271-5964). Thank You.