Supporting Statement Part A Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement Project (QIP) Attestations CMS-10209, OMB 0938-1023

Background

Section 1852(e) of the Social Security Act requires that MA organizations (MAOs) have an ongoing quality improvement program. CMS regulations at 42 CFR 422.152 outline the quality improvement program (QI Program) requirements for MA plans, which includes a number of activities including the development and implementation of both a Quality Improvement Project (QIP) and a Chronic Care Improvement Program (CCIP).

A CCIP is a clinically focused initiative designed to improve the health of a specific group of enrollees with chronic conditions. Each MAO is required to conduct, over a 3-year period, a CCIP that focuses on the effective management of chronic disease for a chronically ill population.

QIPs are initiatives focused on one or more clinical and/or non-clinical areas with the aim of improving health outcomes and beneficiary satisfaction. Each MAO is required to conduct, over a 3-year period, a QIP that addresses one or more of the CMS Quality Strategy Goals.

MAOs must conduct the same CCIP and QIP for all their non-SNP coordinated care plans offered under a specified contract, including employer group plans and Medical Savings Account plans (MSA) and Private Fee for Service (PFFS) plans that have contracted networks. MAOs must also implement a CCIP and QIP for each SNP type/subtype offered under a specified contract.

Non-Rule Related Changes

Over time, CMS found the annual reporting of QIP and CCIP progress reports overly burdensome. In its place, we have transitioned to an annual attestation requirement. MAOs are now required to annually attest that they have ongoing CCIPs and QIPs that meet program requirements electronically via the Health Plan Management System (HPMS).

Final Rule Related Changes

Over time, CMS found its implementation of both QIP and CCIP requirements had become burdensome and duplicative of other quality initiatives. Therefore, the final rule (CMS-4182-F; RIN 0938-AT08) removes the QIP requirement entirely and allow MA organizations to focus on a single quality project, the CCIP. This requirement becomes effective January 1, 2019. Thus, MAOs will only be required to attest that they have an ongoing CCIP that meets program requirements.

The rule related, CCIP only, attestation will require that MA organizations identify what conditions their CCIP projects are focusing on thereby making it subject to the requirements under the PRA.

We believe it is important for CMS to be aware of the clinical focus of the CCIP projects for monitoring purposes. The revised CCIP attestation requirement will be added through sub regulatory guidance upon the effective date of the final rule and upon OMB approval under the PRA process.

Justification

1. <u>Need and Legal Basis</u>

MAOs are required by CMS regulations at §422.152(a)(1), (2), and (3) to have an ongoing QI program that meets CMS requirements and includes at least one CCIP and one QIP. Every MAO must have a QI program that monitors and identifies areas where implementing appropriate interventions would improve patient outcomes and patient safety. The goal of the QI Program is to demonstrate a favorable effect on health outcomes, enrollee satisfaction, and encourage providers to participate in CMS QI initiatives that result in high quality healthcare being delivered to beneficiaries at all times.

2. Information Users

The collected attestation information will be used by CMS Central to ensure that plans are conducting regulatory required CCIP activities.

3. <u>Use of Information Technology</u>

Technology is used in the collection, processing and storage of the data. Specifically, MAOs must attest that they have an ongoing CCIP and QIP and identify the conditions on which these projects focus via CMS' Health Plan Management System (HPMS) annually. The submission is 100% electronic.

4. <u>Duplication of Efforts</u>

This collection does not contain duplication of similar information.

5. <u>Small Business</u>

This collection does not impose a significant impact on small businesses and other entities.

6. <u>Less Frequent Collection</u>

Before 2017, plans were required to annually submit data concerning the progress of their CCIP and QIP projects. Beginning in 2017, plans are no longer required to annually report this data and are only required to attest that they are meeting CMS requirements, which includes

internally documenting progress on an annual basis internally. A less frequent collection would not allow CMS to ensure that annual requirements are being met. This collection allows CMS to ensure that annual requirements are still being met, while also reducing plan burden.

7. <u>Special Circumstances</u>

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it:
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The November 28, 2017 (82 FR 56336), proposed rule (CMS-4182-P, RIN 0938-AT08) serves as the 60-day Federal Register notice. We did not receive any comments pertaining to our proposed requirements. Consequently, we are finalizing them as proposed.

The final rule (CMS-4182-F, RIN 0938-AT08) published on April 16, 2018 (83 FR 16440) and is effective on June 15, 2018.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents associated with this information collection request.

10. Confidentiality

Consistent with federal government and CMS policies, CMS will protect the confidentiality of the requested proprietary information. Specifically, only information within this collection (or attachments thereto) that constitutes a trade secret, privileged or confidential information, (as such terms are interpreted under the Freedom of Information Act and applicable case law), and is clearly labeled as such by the respondent, and which includes an explanation of how it meets one of the expectations specified n 45 CFR Part 5, will be protected from release by CMS under 5

U.S.C. 552(b)(4). Information not labeled as trades secret, privileged, or confidential or not including an explanation of why it meets one or more of the FOIA exceptions in 45 CFR Part 5 will not be withheld from release under section 552(b)(4).

11. <u>Sensitive Questions</u>

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. <u>Burden Estimates (Hours and Wages)</u>

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation	Occupation	Mean Hourly	Fringe Benefits	Adjusted
Title	Code	Wage (\$/hr)	and Overhead	Hourly Wage
			(\$/hr)	(\$/hr)
Compliance	13-1041	33.77	33.77	67.54
Officer				

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

As explained below in Section 15, the currently approved information collection request sets out burden for CCIP and QIP reports. This 2018 package iteration removes the CCIP and QIP reporting requirements/burden and sets out the following rule and non-rule related changes.

Non-Rule Related Changes

In this information collection request, MAOs would no longer be required to submit CCIP and QIP progress reports to CMS annually. In its place, we have transitioned to an annual attestation requirement. By December 31, 2017, MAOs will be required to attest that they have ongoing CCIPs and QIPs electronically via the Health Plan Management System (HPMS).

By transitioning to an attestation requirement, we estimate that it would take no more than 0.25 (no more 0.125 per attestation; QIP and CCIP) hours at \$67.54/hr for a compliance officer to complete their CCIP and QIP attestation electronically. In aggregate, we estimate an annual burden of 187.5 hours (750 MA contracts x 0.25 hr) at a cost of \$12,663.75 (187.5 hr x \$67.54/hr) or \$ 16.89 per MA contract (\$12,663.75 / 750 MA contracts).

Additionally, §§422.152(a)(2) and 422.152(c)(2) state that MA plans must report the status and results of each program. CMS will require a few MAOs (no more than 5 annually) to upload information about the results and status of each program (QIP and CCIP) electronically each year. CMS will provide a template that MA plans may use as a reference for their electronic uploads. However, strict adherence to these templates will not be required. Since we estimate fewer than ten respondents, the information collection requirements are exempt from the requirements of the PRA (5 CFR 1320.3(c)).

Likewise, any follow up questions would be subject to the same number of respondents such that they would also be exempt under the same provision of the PRA's implementing regulations.

Final Rule Related Changes

Our final rule (CMS-4182-F; RIN 0938-AT08) provision, which will become effective January 1, 2019, removes the QIP attestation requirement (see above for our discussion of non-rule related changes) such that MAOs will only be required to attest that they have an ongoing CCIP.

We believe it is important for CMS to be aware of the clinical focus of the CCIP projects for monitoring purposes. Therefore, the CCIP attestation will require that MA organizations identify what conditions their CCIP projects are focusing on. The requirement that MA organizations identify the clinical focus of their CCIP projects will not be effective until the requirement and burden is approved by OMB under the PRA and the final rule becomes effective.

By adding the revised CCIP attestation requirement, we estimate that it would take 0.25 hours at \$67.54/hr for a compliance officer to complete their single CCIP attestation electronically. In aggregate we estimate an annual burden of 187.5 hours (750 MA contracts x 0.25 hr) at a cost of \$12,663.75 (187.5 hr x \$67.54/hr) or \$ 16.89 per MA contract (\$12,663.75 / 750 MA contracts).

Information Collection/Reporting Instruments and Instruction/Guidance Documents

Non-Rule Related

- QIP Screen Shot Electronic Attestation Form¹
- CCIP Screen Shot—Electronic Attestation Form²

Final Rule Related

¹ Expires 1/1/19 when the CMS-4182-F; RIN 0938-AT08 QIP provision is effective

² Expires 1/1/19, when the CMS-4182-F; RIN 0938-AT08 QIP provision is effective, to be replaced by new rule related attestation form

• CCIP Only Screen Shot – Attestation Form (Effective 1/1/19)³

MAOs are currently required to submit two electronic attestation forms annually: one for the CCIP and one for the QIP. The current QIP and CCIP attestation form replaces the former data reporting forms and only requires MAOs to check a box certifying that they have a QIP in progress that meets program requirements laid out in regulation and sub regulatory guidance and check a box certifying that they have a CCIP in progress that meets program requirements laid out in regulation and sub regulatory guidance. When the final rule becomes effective (January 1, 2019), these forms will be replaced by the attached, CCIP only attestation form, such that MAOs would be required to: (1) check a box certifying that they have an ongoing CCIP project in progress that meets the requirements laid out in regulation and sub regulatory guidance and (2) briefly identify (in 500 characters or less) which chronic condition(s) the project is focusing on.

13. Capital Costs

We do not anticipate additional capital costs. CMS requirements do not require the acquisition of new systems or the development of new technology to complete these reports.

14. Cost to Federal Government

Non-Rule Related

MAOs are currently required to annually attest that they have ongoing CCIPs and QIPs electronically via the Health Plan Management System (HPMS). Based on the budgeted amount per review and estimated wages of reviewers and support staff, we estimate it will take a single CMS reviewer no more than 15 minutes (0.25 hours) to review the combined QIP and CCIP submissions from a single plan (This includes 0.125 hours to review a QIP attestation and 0.125 to review a CCIP attestation). We assume a GS grade 13, step 5, with a mean wage of \$51.48/hr, which with an allowance of 100% for overhead and fringe benefits becomes \$102.96/hr. These estimates are based on a the salary of a single CMS reviewer at a GS 13, step 5 salary level in Washington, Baltimore, Arlington locality.⁴

In aggregate, we estimate it would take 187.5 hours (750 MA contracts x 0.25 hr) at a cost of \$19,305 (187.5 hr x \$102.96/hr).

Rule Related

When the final rule becomes effective and when this information collection request is approved by OMB under the PRA, the current form described above will be replaced by the attached CCIP only attestation form, such that MAOs would be required to: (1) check a box certifying that they have an ongoing CCIP project in progress that meets the requirements laid out in regulation and sub regulatory guidance and (2) briefly identify (in 500 characters or less) what condition(s) the project focuses on.

³ Effective 1/1/19, new rule related attestation form, replaces former CCIP attestation

⁴ https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf

Based on the budgeted amount per review and estimated wages of reviewers and support staff, we estimate it will take a single CMS reviewer no more than 15 minutes (0.25 hours) to review each CCIP submission. We assume a GS grade 13, step 5, with a mean wage of \$51.48/hr, which with an allowance of 100% for overhead and fringe benefits becomes \$102.96/hr. These estimates are based on a the salary of a single CMS reviewer at a GS 13, step 5 salary level in Washington, Baltimore, Arlington locality.⁵

In aggregate, we estimate it would take 187.5 hours (750 MA contracts x 0.25 hr) at a cost of \$19,305 (187.5 hr x \$102.96/hr).

15. <u>Changes to Burden</u>

CCIP and *QIP* Reporting Tools (Removed Requirements/Burden)

We are removing the reporting requirement and burden (-28,560 hours). Consistent with this action, we are also removing the following forms that were associated with the 2014 package:

CCIP Screen Shots -- Do Study Act Sections Annual Update

CCIP Screen Shots - Act Section Annual Update.jpg

CCIP Screen Shots - Study Section Annual Update

CCIP Screen Shots - Contract Selection Screen Annual Update

CCIP Screen Shots -- Do Section Annual Update

CCIP Screen Shots - Submission Selection Screen Annual Update

QIP Screen Shots - Act Section Annual Update

QIP Screen Shots - Contract Selection Screen Annual Update

QIP Screen Shots - Do Section Annual Update

QIP Screen Shots - Do Study Act Sections Annual Update

QIP Screen Shots - Study Section Annual Update

QIP Screen Shots - Submission Screen Annual Update

MAOs are no longer required to submit CCIP and QIP progress reports to CMS annually. Previously MAOs were required to report project statuses for both the CCIP and QIP. The annual reports required plans to identify problems, analyze results, and document plans on how to fix those problems in the coming years. CMS no longer collects this information. We have transitioned to an annual attestation.

Non-Rule Related Changes (New Requirements)

In this information collection request, MAOs would no longer be required to submit CCIP and QIP progress reports to CMS annually. In its place, we have transitioned to an annual attestation requirement. By December 31, 2017, MAOs will be required to attest that they have ongoing CCIPs and QIPs electronically via the Health Plan Management System (HPMS).

By transitioning to QIP and CCIP attestations, we estimate that it would take 0.25 (0.125 for each) hours at \$67.54/hr for a compliance officer to complete their QIP and CCIP attestations,

⁵ https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf

which consists of an electronic checkbox. In aggregate, we estimate an annual burden of 187.5 hours (750 MA contracts x 0.25 hr) at a cost of \$12,663.75 (187.5 hr x \$67.54/hr) or \$ 16.89 per MA contract (\$12,663.75 / 750 MA contracts).

Additionally, §§422.152(a)(2) and 422.152(c)(2) state that MA plans must report the status and results of each program. CMS will require a few MAOs (no more than 5 annually) to upload information about the results and status of each program (QIP and CCIP) electronically each year. We believe selecting one plan from each of the five major parent organizations will give us a good idea of what types of projects are being implemented in the industry. In our experience, we have found that the projects are very similar by parent organization. CMS will provide a template that MA plans may use as a reference for their electronic uploads. However, strict adherence to these templates will not be required. Since we estimate fewer than ten respondents, the information collection requirements are exempt from the requirements of the PRA (5 CFR 1320.3(c)).

Likewise, any follow up questions would be subject to the same number of respondents such that they would also be exempt under the same provision of the PRA's implementing regulations.

Final Rule Related Changes (New Requirement and Burden)

Our final rule (CMS-4182-F; RIN 0938-AT08) removes the QIP attestation requirement (see above for our discussion of non-rule related changes) such that MAOs will only be required to attest that they have an ongoing CCIP.

We believe it is important for CMS to be aware of the clinical focus of the CCIP projects for monitoring purposes. Therefore, the CCIP attestation will require that MA organizations identify what conditions their CCIP projects are focusing on. The requirement that MA organizations identify the clinical focus of their CCIP projects will not be effective until the requirement and burden is approved by OMB under the PRA and the final rule becomes effective.

By adding the revised CCIP attestation requirement, we estimate that it would take 0.25 hours at 67.54/hr for a compliance officer to complete their single CCIP attestation, which includes both the check box and text field, electronically. In aggregate, we estimate an annual burden of 187.5 hours (750 MA contracts x 0.25 hr) at a cost of 12,663.75 (187.5 hr x 67.54/hr) or 16.89 per MA contract (12,663.75 / 187.5 MA contracts).

Attestation Instruments (New)

Non-Rule Related

- OIP Screen Shot Electronic Attestation Form⁶
- CCIP Screen Shot—Electronic Attestation Form⁷

Final Rule-Related

⁶ Expires 1/1/19 when the CMS-4182-F; RIN 0938-AT08 QIP provision is effective

⁷ Expires 1/1/19, to be replaced by new rule related attestation form

• CCIP Only Attestation Screen Shot – Attestation Form

Summary of Burden Changes

Non-Rule Related Burden Changes

CY 2014 (Reporting) CY 2017 QIP & CCIP (Attestation)

	No. Respondents	Time (hours per response)	Annual Burden Hours	No. Respondents	Time (hours per response)	Annual Burden Hours
CCIP	952	15	14,280	750	0.125	93.75
Q1P	952	15	14,280	750	0.125	93.75
Total	1,904		28,560	1500		187.5

While the number of respondents has decreased by 404 (1,904 - 1500), our time estimate has decreased by 28,372.5 hours (28,560 hr - 187.5 hr).

<u>Cost</u>

CY 2014 (Reporting)

CY 2017 (Attestation)

	Annual Burden Hours	Wage (\$/hr)	Cost (\$)	Annual Burden Hours	Wage (\$/hr)	Cost (\$)
CCIP	14,280	\$55	785,400	93.75	67.54	6,331.88
Q1P	14,280	\$55	785,400	93.75	67.54	6,331.88
Total	28,560		1,570,800	187.5		12,663.75

Along with our decreased time estimate (-28,372.5 hr), our wage estimate is now based on BLS data which has been adjusted to account for fringe benefits and overhead. In this regard, our wage figure has increased by \$12.54/hr (from \$55/hr to \$67.54/hr). Overall, our cost estimate has decreased by \$1,558,136.25 (\$1,570,800 - \$12,663.75).

Final Rule Related Burden Changes

<u>Time</u>

CY 2014 (Reporting)

CY 2017 CCIP only (Attestation)

	No. Respondents	Time (hours per response)	Annual Burden Hours	No. Respondents	Time (hours per response)	Annual Burden Hours
CCIP	952	15	14,280	750	0.25	187.5
Q1P	952	15	14,280	0	0	0
Total	1,904		28,560	750		187.5

While the number of respondents has decreased by 1,154 (1,904 - 750), our time estimate has decreased by 28,372.5 hours (28,560 hr - 187.5 hr).

<u>Cost</u>

CY 2014 (Reporting)

CY 2017 (Attestation)

	Annual Burden Hours	Wage (\$/hr)	Cost (\$)	Annual Burden Hours	Wage (\$/hr)	Cost (\$)
CCIP	14,280	\$55	785,400	187.5	67.54	12,663.75
Q1P	14,280	\$55	785,400	0	0	0
Total	28,560		1,570,800	187.5		12,663.75

Along with our decreased time estimate (-28,372.5 hr), our wage estimate is now based on BLS data which has been adjusted to account for fringe benefits and overhead. In this regard, our wage figure has increased by \$12.54/hr (from \$55/hr to \$67.54/hr). Overall, our cost estimate has decreased by \$1,558,136.25 (\$1,570,800 - \$12,663.75).

16. Publication/Tabulation Dates

CMS anticipates that there will be no public reports on CCIP and QIP findings.

17. <u>Expiration Date</u>

CMS is not requesting an exemption from displaying the expiration date. The expiration date will be added to the attestation screens.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This information collection does not employ any statistical analyses.