Quality Standards – Quality Improvement Strategy Supporting Statement

Supporting Statement for Information Collection: Quality Improvement Strategy Implementation Plan, Progress Report Form and Modification Summary Supplement

(CMS-10540/OMB Control number – 0938-1286)

A. Background

A Qualified Health Plan (QHP) issuer participating in an Exchange for two or more consecutive years must implement and report on a quality improvement strategy (QIS) or strategies, in accordance with section 1311(g) of the Patient Protection and Affordable Care Act (PPACA), to cover all its QHPs. The QIS requirements apply to all issuers offering QHPs through the individual marketplace or through the Small Business Health Options Program (SHOP). All QHP issuers must comply with the following requirements:

(1) Implement a quality improvement strategy, defined as a payment structure that provides increased reimbursement or other incentives.
(2) Implement at least one of the following:
   i. Activities for improving health outcomes,
   ii. Activities to prevent hospital readmissions,
   iii. Activities to improve patient safety and reduce medical errors,
   iv. Wellness and health promotion activities, and
   v. Activities to reduce health and health care disparities.
(3) Comply with guidelines established by the Secretary of Health and Human Services (HHS) in consultation with experts in health care quality and stakeholders.
(4) Report strategy progress to the applicable Exchanges on a periodic basis.

All Exchanges are required to evaluate quality improvement strategies for issuer applicants. State-based Exchanges (SBEs)[1] will evaluate the strategies of the issuers applying to offer QHPs in their respective Exchanges. The Centers for Medicare & Medicaid Services (CMS) will evaluate the strategies of issuers applying to offer QHPs in most Federally-facilitated Exchanges (FFEs).[2] In FFEs where States perform plan management, issuers applying to offer QHPs will undergo a joint review of their quality improvement strategies by the State and the FFE. CMS requests approval from the Office of Management and Budget (OMB) for the renewal of the information collection associated with the QIS requirements.

[1] An SBE is an Exchange model in which a State establishes and operates its own Health Insurance Exchange, for both the individual and small group markets, pending approval by CMS.
[2] FFEs are Exchanges established and operated by CMS for individual and small group market coverage.

B. Justification

1. Need and Legal Basis

The PPACA establishes requirements to support the delivery of quality health care coverage for health insurance issuers offering QHPs through the Exchanges.[3] Section 1311(c)(1)(E) of the PPACA specifies that certification as a QHP for participation in an Exchange is contingent upon each health plan implementing a QIS. Section 1311(g)(1) of the PPACA, entitled "Rewarding Quality Through Market-Based Incentives," describes this strategy as a payment structure providing increased reimbursement or other incentives for improving health outcomes of plan enrollees, implementing activities to prevent hospital readmissions, improving patient safety and reducing medical errors, promoting wellness and health, and/or implementing activities to reduce health and health care disparities.

Section 1311(g)(2) of the PPACA requires the Secretary to develop guidelines in consultation with health care quality experts and stakeholders, including periodic reporting of the activities that the QHP issuer has conducted to implement a QIS, to the applicable Exchange, as described in section 1311(g)(3). 45 C.F.R. § 155.200(d) directs Exchanges to evaluate quality improvement strategies, and 45 C.F.R. § 156.200(b) directs issuers to implement and report on a QIS or strategies consistent with section 1311(g) standards as a QHP certification criteria for participation in an Exchange.

The statutory QIS requirements extend to all Exchange types, including the FFEs, FFEs where States perform plan management, and SBEs. The QIS requirements and standards that are used for the FFEs provide the starting point for SBEs to build upon. SBEs have the flexibility to establish the timeline, format, validation, and other requirements for the annual QIS information submission by issuers that participate in their respective Exchanges.

In accordance with Section 1311(g) of the PPACA, CMS established the QIS requirements in the HHS Notice of Benefit and Payment Parameters for 2016.[4] CMS requests OMB clearance for the renewal of this Information Collection Request (ICR) so that CMS may continue to collect the information needed to continue implementing the QIS requirements and standards established in the HHS Notice of Benefit and Payment Parameters for 2016; Final Rule.

The separation of the QIS form into a separate Implementation Plan, Progress Report and Modification Summary is intended to decrease overall burden on issuers. With these separate forms, issuers would no longer need to complete and resubmit an Implementation Plan every year (which is currently the process). Issuers would only submit the Implementation Plan form in the first year of a QIS, and then issuers would submit the Progress Report form in each subsequent year (with the Modification Summary Supplement as necessary). This adjustment will eliminate the need for issuers to enter and submit unchanged data, and allow them to focus

[3] A QHP issuer is a health insurance issuer that offers a QHP in accordance with a certification from an Exchange. All issuers subject to QIS requirements are QHP issuers, and are referred to as "issuers" in this and other QIS materials as noted in the Final Rule on Marketplace and Insurance Market Standards for 2015 and Beyond, available at: http://www.gpo.gov/fdsys/pkg/FR-2014-05-27/pdf/2014-11657.pdf.

[4] This final rule was published in February 2015 and is available here: https://www.federalregister.gov/documents/2015/02/27/2015-03751/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2016.

their time on reporting new progress achieved for the QIS. All changes will be communicated to issuers via email, webinars and Technical Guidance and User Guide.

2. Information Users

Since calendar year 2016 (for the 2017 Plan Year), CMS has been collecting QIS information from issuers on an annual basis to evaluate the compliance and adequacy of issuers' QIS implementation efforts, as required by Section 1311(c) of the PPACA entitled "Rewarding Quality Through Market-Based Incentives." CMS will use the issuers' validated information to evaluate issuers' QIS submissions for compliance as a condition of QHP certification. Though the QIS requirements apply to all issuers offering QHPs through an Exchange (both Individual Exchanges and SHOP Exchanges), CMS will only evaluate the QIS forms for issuers applying to offer QHPs in FFEs, including FFEs where States perform plan management. SBEs will evaluate the QIS submissions of the issuers applying to offer QHPs in their State's Exchange. SBEs, including SBEs on the Federal Platform (SBE-FPs), have the flexibility to establish the timeline, reporting form, validation of data, and other requirements related to annual submission of QIS data by the issuers participating in their respective Exchanges.

The goal of the QIS form is to collect QIS information from issuers. This information will demonstrate compliance with Section 1311(c)(1)(E) of the PPACA. It will also facilitate understanding of the issuer's payment structure framework that provides increased reimbursement or other market-based incentives for the implementation of activities related to the topics specified in Section 1311(g) of the PPACA.

3. Use of Improved Information Technology and Burden Reduction

All information collected from an issuer about its QIS will be submitted electronically. CMS will analyze the information electronically and will communicate with each issuer, if necessary, by email and telephone.

4. Duplication of Efforts

This information collection does not duplicate any other federal effort.

5. Impact on Small Businesses or Other Small Entities

This information collection will not have a significant impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

CMS must collect QIS information on an annual basis to evaluate an issuer's compliance with the conditions for QHP certification and annual recertification through the Exchanges according to the PPACA. Less frequent information collection would result in non-compliance with federal regulations.

7. Special Circumstances

There are no special circumstances associated with this information collection.

8. Federal Register Notice/Outside Consultation

CMS has refined the QIS form, separating it into separate Implementation Plan and Progress Report forms, based on feedback from issuers, Exchanges, and other stakeholders received since the last version of the form was published in the spring of 2019. CMS used the following sources to identify refinements: direct feedback from issuers and analysis of issuers' experiences completing and submitting the QIS form for evaluation, feedback received during QIS webinars, and inquiries received by the QIS Help Desk. CMS also considered lessons learned throughout the QIS evaluation process for each plan year to inform its refinements.

The refinements are intended to improve an issuer's ability to meet the QIS requirements in the plan year and increase efficiencies to reduce issuer burden by making the QIS form more straightforward.

CMS has received questions and recommendations during its annual QIS webinars for issuers, state representatives and Account Managers regarding QIS requirements, the QIS form, the QIS evaluation methodology, and the QIS submission process and timeline. CMS supported a weekly QHP webinar series, during which it periodically fielded QIS-related questions. CMS considered these inputs when identifying recommended revisions to the QIS form.

Additionally, CMS provides technical assistance in the form of direct responses to inquiries received via CMS' Marketplace Service Desk (MSD) Help Desk and Marketplace Quality Initiatives (MQI) email inbox, as well as through targeted outreach activities and materials (e.g., frequently asked questions [FAQs]). CMS also uses these interactions with issuers to identify potential areas for improvement and inform CMS' revisions to the QIS form.

In 2018, OMB approved the QIS form (OMB Control # 0938-1286) for two years, noting a comment shared by two stakeholder groups about the burden associated with completing the requirement that issuers populate the Implementation Plan section of the QIS form each year when reporting on progress.

To alleviate this burden, CMS has separated the QIS form into three separate parts: an Implementation Plan form, a Progress Report Form, and a Modification Summary Supplement to streamline information collection and reduce burden on issuers.

All issuers will be required to submit a baseline Implementation Plan for the 2022 Plan Year, which CMS will keep on file for the duration of the QIS. In subsequent years, issuers reporting progress of an existing QIS will no longer be required to complete the Implementation Plan form and will only be required to submit a Progress Report form and, if applicable, the Modification Summary to modify their existing QIS.

CMS will provide substantial outreach and technical assistance to inform issuers of this change, (e.g., the QIS Technical Guidance and User Guide, webinars, responses to Help Desk tickets).

The QIS Implementation Plan form, Progress Report form and Modification Summary Supplement forms were available during a 60-day public comment period associated with the Paperwork Reduction Act (PRA). While no comments were received specifically on these forms, an anonymous stakeholder shared support for the separation of these forms while commenting on another quality form available for public comment. During the 30-day public comment period, America's Health Insurance Plans (AHIP) submitted one comment voicing support for the

separation of forms and burden reduction for issuers. AHIP also expressed concern with the submission timeline, however, the QIS submission deadlines are part of the broader QHP certification process timelines which the QIS program must align with. CMS will continue to encourage issuers to submit preliminary data in initial submissions, and update data in the final QIS submission.

In response to the COVID-19 pandemic, in April 2020, CMS announced flexibility for QHP issuers that are eligible to report for the QIS programs for PY2021 QHP Certification Period, to suspend activities related to the collection and reporting of data for the QRS, QHP Enrollee Survey and QIS. As such, CMS removed any reference to PY2021 data in the separated QIS forms.

9. Payment/Gift to Respondents

Respondents will not receive payments or gifts for completion of this data collection.

10. Confidentiality

No personal information will be collected. All information will be kept private to the extent allowed by applicable laws/regulations.

11. Sensitive Questions

No sensitive information will be collected.

12. Burden Estimates (Hours & Wages)

The burden estimate shows the estimated labor hours and costs associated with respondents (i.e., issuers) collecting and reporting information to an Exchange in accordance with the proposed QIS form, but not the burden of implementing a QIS.

Burden Estimate for 250 Issuers

The estimate assumes 250 issuers (all eligible issuers in all Exchanges, excluding Stand-alone Dental Plans [SADPs]), and covers the annual costs for an issuer over a three-year period (2022 through 2024). This estimate is based on historical data of the required number of issuers that submitted a QIS in the 2020 Plan Year, CCIIO's estimated number of issuers participating in the Exchange for the 2021 Plan Year, and accounts for additional issuers entering eligibility over the next three years.

CMS' estimate assumes participation of all eligible issuers in all Exchange types and QHP coverage types. (SADPs are not subject to the QIS requirements and are, therefore, excluded from the estimate.) The estimate relies on the assumption that all 250 issuers will complete and submit the necessary portions of the relevant QIS form during each of those years.

As noted above, all issuers will submit a baseline Implementation Plan form for the 2022 Plan Year to establish an Implementation Plan on file. They will not have to recomplete and resubmit this form in subsequent years unless the issuer is implementing a new QIS.

For the 2023 Plan Year and beyond, only issuers implementing a new QIS will complete and submit the Implementation Plan Form. All other issuers will submit a Progress Report and Modification Summary (if modifying the QIS for the upcoming year).

The level of effort required to complete each form is broken out in Exhibit 1 to show the annual estimated hour burden and cost burden for issuers. Further information on the burden estimate is provided after Exhibit 1.

Exhibit 1. QIS Annual Estimated Hour Burden and Cost Burden for One Issuer

Step #	Step Name	Average Hourly Labor Costs[5] (Hourly Rate + 100% Fringe Benefits)	Hour Burden	Total Cost Burden (Per Issuer)
Implementation Year				
1	Gather Information	$80.94	38	$3,075.76
2	Develop Response and Submit Form	$83.17	6	$499.04
	Total		**44**	**$ 3,574.80**
Reporting Year				
1	Gather Information	$81.98	13	$1065.76
2	Develop Response and Submit Form	$83.73	5	$418.64
	Total		**18**	**$1,484.40**
	Total over 3 years		**80**	**$6543.60**
	Averaged over 3 years		**27**	**$2181.20**

For one issuer, the burden to collect and report information for its QIS for three years is estimated to take approximately 80 hours and cost approximately $6,543.60. This assumes all issuers submit one Implementation Plan form and two Progress Report forms during the three-year period.

For all estimated 250 issuers combined, the burden to collect and report information for their quality improvement strategies for one implementation year is estimated to take approximately 11,000 hours and cost approximately $893,700. The burden to collect and report information for all issuers' quality improvement strategies for one progress report year is estimated to take approximately 4,500 hours and cost approximately $371,100. Assuming one implementation year and two years of reporting progress, the burden for all 250 issuers to collect and report information for their quality improvement strategies for three years is estimated to take approximately 20,000 hours and cost approximately $1,635,9000.

Additional Burden Estimate Information

The burden estimate is based on estimates provided by a selected subset of fewer than 10 issuers. The sample was composed of issuers that have QIS reporting experience. Each issuer interviewed estimated labor hours and wage rates for each position involved in the QIS information collection and reporting process. A fringe benefit rate of 100 percent was applied to the hourly wage rates.

[5] http://www.bls.gov/oes/current/oes_stru.htm.

CMS has taken steps to significantly reduce the overall burden on issuers by separating the QIS form into separate Implementation Plan and Progress Report forms, only requiring issuers to submit the relevant form based on the issuer's QIS submission type that year.

CMS continues to estimate the number of QHP issuers submitting quality improvement strategies for 2022 through 2024 to be 250 issuers. Maintaining the number of issuers but decreasing the hours and type of staff required to complete the QIS submission, results in an overall decrease in burden. As issuers become more familiar with their quality improvement strategies and are reporting on progress year over year, they can use primarily mid-level staff, who will spend less time overall completing the QIS forms.

See Exhibit 2 for the effect of the reduced issuer staff hours on overall annual burden reduction.

Exhibit 2: Annual Burden Reduction Due to Reduced Issuer Staff Hours

Source	No. of QHP Issuers	Estimated Burden Hours per Implementation Year	Total Cost per Issuer per Implementation Year	Estimated Burden Hours per Progress Report Year	Total Cost per Issuer (Progress Report year)	Total Cost for all Issuers per Year [6]
Estimated 2020	250	12,000	$5,344	12,000	$5,344	$1,336,000
Estimated 2022	250	11,000	$3,574.80	4,500	$1,484.40	$545,300
Total Reduction	N/A	1,000	$176,920	7,500	$3,859.60	-$790,700

The burden estimate accounts only for the burden of information collection and reporting activities during the QHP Application Period.

During the QHP Application Period, issuers submit information regarding their QIS to the Exchanges via the QIS form. In the first year of an issuer's QIS participation, it is required to submit a QIS Implementation Plan via the QIS form that describes the issuer's quality improvement strategy or strategies for all its QHPs offered through the FFE, including QHPs offered in FFEs where States perform plan management. The following year, and each year thereafter (until an issuer submits a QIS Implementation Plan for a new strategy), the issuer is required to submit a QIS Progress Report via the QIS form, which describes implementation progress related to its QIS. The issuer is also required to submit a QIS Implementation Plan, identical to the previous year's QIS Implementation Plan, in conjunction with its QIS Progress Report (within the same Implementation Plan and Progress Report form) to verify its original QIS has not changed.

Exhibit 3 shows the information collection and reporting steps for the QIS during the QHP Application Period, which serves as the basis for the burden estimate.

[6] Note that for the 2022 estimates, this annualized measure is a result of averaging one implementation plan year and two years of reporting progress.

Exhibit 3. QIS Information Collection and Reporting Steps

Step #	Step Name	Implementation Plan Step Description	Progress Report Step Description
1	Gather Information	To develop the response for the Implementation Plan, the issuer gathers information from within its organization pertaining to the following elements: The issuer proposes a QIS that meets all legislative requirements; identifies the current payment models used across Exchange product lines; identifies the data sources used to identify enrollee population needs; provides a rationale for how the strategy will address the needs of the enrollee population; proposes goals, performance measures, and related targets; describes plans to implement activities designed to meet the performance targets; defines an implementation timeline; identifies known or anticipated barriers; and provides mitigation/action plans to support successful implementation of its QIS activities.	To develop the response for the Progress Report, the issuer gathers information from within its organization pertaining to the following elements: The issuer describes activities conducted to implement its QIS with a focus on its progress toward meeting stated goals and performance targets; updated data on performance measures and targets; and descriptive information on why targets were or were not met.
2	Develop Responses and Submit Implementation Plan/ Progress Report	The issuer synthesizes the information collected, electronically completes responses in the form, and submits the Implementation Plan to the Exchange. The Implementation Plan includes character limits for each response field.	Same as the Implementation Plan.

Since the elements for the Implementation Plan and the Progress Report forms are different, CMS assumes the issuer's level of effort will be different each year. Therefore, CMS averaged the burden estimate needed to complete the different sections to produce an annualized estimate for each issuer. The average was weighted based on the current assumption that each issuer will submit one QIS Implementation Plan and two QIS Progress Reports during the three-year period.

The estimate assumes that, each year, each issuer will submit only one QIS to cover all of its respective QHPs operating through an Exchange. CMS will conduct up to two rounds of QIS review concurrent with the two rounds of QHP Application review: First Review and Second Review. An issuer whose initial QIS submission meets the requirements will not undergo a second review. An issuer whose initial QIS submission does not sufficiently meet the requirements during the first review will need to resolve any issues, make clarifications, and re-submit a revised form during the second QIS submission window.

The burden incurred by issuers to revise and re-submit the Implementation Plan and Progress Report form is not included in this burden estimate. The OMB regulation implementing PRA (5 C.F.R. § 1320.3(h)) defines categories of information collection that generally are not deemed to constitute information requiring OMB clearance. The OMB definition of information that does not require clearance includes "information solicited through non-standardized follow-up questions designed to clarify responses to approved collections of information." Therefore, the information CMS requires from issuers to revise and re-submit a form is considered to be information that does not require OMB clearance.

This estimate also does not account for the burden incurred by SBEs associated with collecting and evaluating the information reported by issuers to fulfill the QIS requirements.

13. Capital Costs

No additional capital costs are expected. Neither the acquisition of new systems nor the development of new technology is required to complete these reports.

14. Cost to Federal Government

CMS estimates that the operations, maintenance, and information collection costs to the federal government associated with this information collection include contract costs for the QIS collection. CMS issued a request for proposal (RFP) to a contractor to manage all incoming information. The estimated annual cost to the federal government for QIS information collection is $**372,643.79**. This cost estimate reflects the costs associated with collecting information from issuers offering QHPs only in States operating as FFEs, including FFEs where States perform plan management.

15. Explanation for Program Changes or Adjustments

This is a revision of a currently approved information collection required by the PPACA. The separation of the QIS form into separate Implementation Plan and Progress Report forms is in response to OMB's suggestion in the previous Notice of Action dated 11/28/2018 to decrease issuer burden associated with resubmitting an Implementation Plan every year. The separation of the QIS form into these distinct parts is expected to decrease the number of issuer hours (particularly management level staff) from 144 hours over three years to 80 hours over three years, decreasing the overall burden and cost.

16. Publication/Tabulation Dates

At this time, CMS does not expect that the information collected in the annual reports will be published or shared with other agencies.

17. Expiration Date

The expiration date and OMB control number will appear on the first page of each instrument (top right corner).