Quality Standards – Quality Improvement Strategy Supporting Statement

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

(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, and/or
    iv. Wellness and health promotion activities.
(3) Implement at least one QIS that includes activities to reduce health and health care disparities.[1]
(4) Comply with guidelines established by the Secretary of Health and Human Services (HHS) in consultation with experts in health care quality and stakeholders.
(5) 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)[2] 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).[3] 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] Beginning with the 2024 Plan Year, issuers are required to address at least two topic areas in their quality improvement strategies on file with "Reduce health and health care disparities" as one of the topic areas, as cited in the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 (87 FR 27208).
[2] 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.
[3] 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.[4] 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.[5] CMS updated the QIS requirements to include a new guideline under which QHP issuers would be required to address health and health care disparities as a specific topic area within their QIS, in addition to at least one other topic area in the HHS Notice of Benefit and Payment Parameters for 2023.[6] 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 and HHS Notice of Benefit and Payment Parameters for 2023; Final Rule.

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[4] 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

[5] 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.

[6] This final rule was published in May 2022 and is available here: https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023

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's 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

Upon approval of the Information Collection Request (ICR) under OMB Control Number 0938-1286 in 2021, CMS refined the QIS form, separating it into three documents including the Implementation Plan, Progress Report, and Modification Summary Supplement forms. This

refinement streamlined information collection and reduced burden on issuers, based on feedback received from issuers, Exchanges, and other interested persons. To identify additional areas of refinement for the QIS forms addressed in this ICR, CMS used the following sources: direct feedback from issuers and analysis of issuers' experiences completing and submitting the QIS forms for evaluation, feedback received during QIS webinars, and inquiries received via CMS' Marketplace Service Desk (MSD) Help Desk and Marketplace Quality Initiatives (MQI) email inbox. 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, by increasing the user interpretability of the QIS forms.

CMS has received questions and recommendations during its annual QIS webinars for issuers, state representatives and Account Managers regarding QIS requirements, the QIS forms, 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 forms.

Additionally, CMS provides technical assistance in the form of direct responses to inquiries received via the MSD Help Desk, 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 forms.

We updated this information collection request to account for the associated burden of the refinements to the QIS forms. This includes changes to the requirement that issuers select health and health care disparities as a topic area beginning in Plan Year 2024 as finalized in the HHS Notice of Benefit and Payment Parameters for 2023; Final Rule.

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

The QIS forms were available during a 60-day public comment period (from September 28 through November 28, 2023) associated with the PRA. CMS did not receive comments during the 60-day public comment period.

Since publishing the QIS forms for the 60-day public comment period, CMS completed its evaluation of QIS submissions for the Plan Year 2024 QHP Application Period. Based on common errors in QIS submissions, CMS has incorporated the following changes into the QIS forms to facilitate issuer completion of the QIS forms and to reduce the frequency of issuer deficiencies: clarifying response prompts and adding supplemental guidance into the QIS forms; including a response prompt to indicate the QIS population target for issuers implementing a strategy to address the reduce health and health care disparities topic area; refining QIS form format to improve congruence across the QIS forms (e.g., requesting issuers provide the consensus-based entity (CBE) for quality measures, when applicable).

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 forms, but not the burden of implementing a QIS. The adjustments made to the QIS form after the 60-day public comment period have no significant impact on the burden estimate.

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 (2024 through 2027). 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 forms during each of those years.

Issuers operating on an Exchange who meet the QIS participation criteria and have an existing QIS on file, will not have to recomplete and resubmit an Implementation Plan form during the three-year period unless the issuer is implementing a new QIS.

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). CMS estimates that approximately 20% of all eligible issuers will complete an Implementation Plan form during the three-year period (i.e., an Implementation Year), while 80% of issuers submit only Progress Report forms (i.e., Reporting Year).

The level of effort required to complete QIS forms by year-type 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 for One Issuer

Step #	Step Name	Hour Burden
Implementation Year		
1	Gather Information	38
2	Develop Response and Submit Form	6
	Total	44
Reporting Year		
1	Gather Information	13
2	Develop Response and Submit Form	5
	Total	18
Total over 3 years (Existing Issuer)		54
Total over 3 years (New Issuer)		80
Averaged over 3 years[7]		20

Exhibit 2. QIS Annual Estimated Hour Burden and Cost Burden for Issuers

Step #	Step Name/Labor Categories Involved in Step	Hourly Labor Costs[8] (Median Hourly Rate + 100% Fringe Benefits)	Hour Burden per response	Cost Burden per response	Number of Respondents	Total Hour Burden	Total Cost Burden
1	Gather Information		38	$3456.39	50	1900	$172,819.40
	General and Operations Manager	$164.60	.8	$131.68	50	40	$6,584.00
	Medical and Health Services Managers	$141.54	3.4	$481.24	50	170	$24,061.80
	Medical Records and Health Information Analyst	$84.16	7.8	$481.24	50	390	$32,822.40
	Business Operations Specialist, Other	$80.24	25.2	$2,022.05	50	1260	$101,102.40
	Medical Director	$206.22	.8	$164.98	50	40	$8,248.80
2	Develop Response and Submit Form		6.2	$675.26	50	310	$33,762.80
	General and Operations Manager	$164.60	.3	$49.38	50	15	$2,469.00
	Medical and Health Services Managers	$141.54	.4	$56.62	50	20	$2,830.80
	Medical Records and Health Information Analyst	$84.16	.5	$42.08	50	25	$2,104.00
	Business Operations Specialist, Other	$80.24	4	$320.96	50	200	$16,048.00
	Medical Director	$206.22	1	$206.22	50	50	$10,311.00
	Implementation Year Total		**44**	**$4,131.64**	**50**	**2210**	**$206,582.20**
1	Gather Information		13.4	$1,116.59	250	2680	$279,148.00

[7] Assuming 20% of eligible issuers are new and reporting in their implementation year.
[8] http://www.bls.gov/oes/current/oes_stru.htm

Step #	Step Name/Labor Categories Involved in Step	Hourly Labor Costs (Median Hourly Rate + 100% Fringe Benefits)	Hour Burden per response	Cost Burden per response	Number of Respondents	Total Hour Burden	Total Cost Burden
	General and Operations Manager	$164.60	0	$0.00	250	0	$0.00
	Medical and Health Services Managers	$141.54	.2	$28.31	250	40	$7,077.00
	Medical Records and Health Information Analyst	$84.16	1	$84.16	250	200	$21,040.00
	Business Operations Specialist, Other	$80.24	12	$962.88	250	2400	$240,720.00
	Medical Director	$206.22	.2	$41.24	250	40	$10,311.00
2	Develop Response and Submit Form		4.7	$553.44	250	940	$138,359.00
	General and Operations Manager	$164.60	.3	$49.38	250	75	$12,345.00
	Medical and Health Services Managers	$141.54	.8	$113.23	250	200	$28,308.00
	Medical Records and Health Information Analyst	$84.16	.3	$25.25	250	75	$6,312.00
	Business Operations Specialist, Other	$80.24	2.5	$200.60	250	625	$50,150.00
	Medical Director	$206.22	.8	$164.98	250	160	$41,244.00
	Reporting Year Total		**18**	**$1670.03**	**250**	**3620**	**$417,507.00**

For a new issuer, the burden to collect and report information for its QIS for three years is estimated to take approximately 80 hours and cost approximately $7,472. This assumes those issuers submit one Implementation Plan form and two Progress Report forms during the three-year period.

For an existing issuer, the burden to collect and report information for its QIS for three years is estimated to take approximately 54 hours and cost approximately $5,010. This assumes those issuers submit three Progress Report forms during the three-year period, and Modification Summary Supplement forms, if necessary. For the projected 50 new issuers (i.e., 20% of all eligible issuers), the burden to collect and report information for their quality improvement strategies for one implementation year is estimated to take approximately 2,210 hours and cost approximately $206,582. The burden to collect and report information for all 250 issuers' quality improvement strategies for one progress report year is estimated to take approximately 4,500 hours and cost approximately $417,507. Total burden for all 250 issuers to collect and report information for their quality improvement strategies for three years is estimated to take approximately 14,880 hours and cost approximately $1,375,602 (assuming one implementation year and two years of reporting progress for new issuers, and three years of reporting progress for existing issuers).

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 provided labor hours and the required labor category for each position involved in the QIS information collection and reporting process. Median base salary data was gathered from the Bureau of Labor Statistics[9] for each defined labor category. A fringe benefit rate of 100 percent was applied to the median hourly wage rates.

CMS has successfully reduced 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 for that year.

CMS continues to estimate the number of QHP issuers submitting quality improvement strategies for 2024 through 2027 to be 250 issuers. Maintaining the number of issuers but decreasing the volume of Implementation Form QIS submissions, results in an overall decrease in burden.

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 forms. In the first year of an issuer's QIS participation, it is required to submit a QIS Implementation Plan 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 form, which describes implementation progress related to its QIS.

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.

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

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/ Modification Summary Supplement	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 new issuer will submit one QIS Implementation Plan and two QIS Progress Reports during the three-year period, and each existing issuer will submit three QIS Progress Reports.

The estimate assumes that each year, each issuer will submit a single 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. CMS does not collect QIS data from SBE issuers nor does the state submit this information to CMS.

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 **$514,488**. 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

The total issuer hour and cost burden over the three-year period covered by the Information Collection Request (ICR) under OMB Control Number 0938-1286 proposed for 2024 is expected to decrease as a result of reduced Implementation Years. All eligible issuers currently have a quality improvement strategy on file; hence, Implementation Years would primarily apply to new issuers or issuers who have become reporting eligible. Implementation Years may also apply to issuers who opt to implement a new QIS in addition to their existing strategy or to replace a discontinued strategy. The burden for these issuers is absorbed into the estimates for Progress Reporting.

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

16. Expiration Date

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

17. Publication/Tabulation Dates

This collection of information is not intended for publication In the future, CMS may propose an approach to publishing deidentified data through the rulemaking process.

CMS intends to seek public comment on the approach for publishing QIS data via the HHS Notice of Benefit and Payment Parameters. If finalized, data from the QIS ICR will be published and accessible to the public here: https://www.cms.gov/medicare/quality/health-insurance-marketplace-initiatives.