Quality Standards – Quality Improvement Strategy Supporting Statement

Quality Improvement Strategy Implementation Plan and Progress Report Form

(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 non-substantive change to makes updates to the information collection burden associated with the QIS for Plan Year 2021. The non-substantive change does not introduce new policy or any fundamental program changes. This non-substantive change reduces burden for this year (2020) and is being submitted for approval by OMB as a result of the recent CMS decision to suspend data collection for the QIS for Plan Year 2021[3].

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[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.

[3] COVID-19 Marketplace Quality Initiatives memo available at https://www.cms.gov/files/document/covid-qrs-and-marketplace-quality-initiatives-memo-final.pdf

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.

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 and Multi-State Plan (MSP) options

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[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.

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

A 60-day Notice was published in the federal register on May 18 (83 FR 23280). CMS received a total of three comment submissions: one trade association, one health plan, and one anonymous commenter. Comments have been addressed in Appendix A.

To develop the initial QIS burden estimates, CMS worked with a variety of experts to implement the QIS requirements. CMS contracted with Booz Allen Hamilton (Booz Allen) for consultation and management support related to QIS implementation and evaluation. In addition, Booz Allen organized a QIS Technical Expert Panel (TEP) that continues to provide routine input on QIS technical and methodological issues. The QIS TEP membership is composed of QHP issuer representatives, Exchange and State insurance administrators, health plan accreditors, health care quality improvement and payment reform experts, and federal representatives. The QIS TEP met in December 2013, April 2014, July 2014, December 2014, and February 2015. In addition, CMS

periodically sends email updates and requests virtual feedback from the QIS TEP.

CMS also conducted a pilot test consisting of: (1) two interviews with participating issuer organizations and an SBE, (2) generating a mock QIS Implementation Plan and Progress Report form (QIS form) (formerly called the "QIS Plan Template and Reporting Template") submissions, and (3) conducting evaluations of the mock submissions. CMS held listening sessions with Exchanges, issuers, and issuer associations. Finally, CMS distributed the *Quality Improvement Strategy: Technical Guidance and User Guide for the 2017 Coverage Year* (Technical Guidance/User Guide) for review as part of the HHS document publication clearance process, with many entities providing comments. All of the aforementioned activities informed the development of the QIS requirements.

To inform the initial QIS burden estimates, CMS collected feedback via fewer than nine individual interviews, with issuer representatives and requested feedback during the pilot test. The updated burden estimate within this Supporting Statement was conducted using the Employment Cost Index published by the U.S. Department of Labor's Bureau of Labor Statistics to update the cost to 2017 dollars.[5] CMS did not revise the number of hours necessary to collect QIS information, as the information collected on the revised QIS form does not substantively differ from the information collected on the initial QIS form (OMB 0938-1286).

CMS modified the current revised QIS form based on feedback from issuers, Exchanges, and other stakeholders, which it had received since the QIS form was made publicly available in the spring of 2016. 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 overview webinars and QIS training webinars, and inquiries received by the QIS Help Desk. CMS also considered lessons learned throughout the QIS evaluation process for each plan year, including the QIS evaluation results, 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 typically conducts three QIS overview webinars ahead of each QHP Application Submission and Review Period (QHP Application Period): one for issuers, one for States, and one for Account Managers. During the question and answer portion of each overview webinar during the past two years, CMS received questions regarding the 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 also conducts evaluation training webinars and QIS training webinars for issuers in the FFEs and FFEs where States perform plan management. CMS received questions and recommendations from these stakeholders and 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., issuer- and Exchange-focused webinars). For example, in advance of the each QHP Application Period, CMS received questions from issuers regarding modifying existing QIS Implementation Plans. Specifically, issuers asked what modifications can be made to a QIS Implementation Plan

[5] https://www.bls.gov/ncs/ect/escalator.htm

while continuing with an existing QIS, and what modifications require implementation of a new QIS. CMS identifies and considers frequently asked questions (FAQs) like these examples, as well as inputs obtained from its management of the QIS Help Desk, to distinguish areas for improvement and inform CMS' revisions to the QIS form.

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. 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 (2019 through 2021). This estimate is based on historical data of the required number of issuers that submitted a QIS in the 2018 Plan Year, CCIIO's estimated number of issuers participating in the Exchange for the 2019 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 QIS form during each of those years. Exhibit 1 shows 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 2018 and 2019) and Cost Burden for One Issuer

Step #	Step Name	Average Hourly Labor Costs (Hourly Rate + 100% Fringe Benefits)	Hour Burden	Total Cost Burden (Per Issuer)
1	Gather Information	$107.43	41	$4,405
2	Develop Response and Submit Form	$134.23	7	$940
	Total		**48**	**$5,344**

For one issuer, the burden to collect and report information for its QIS for three years is estimated to take approximately 96 hours and cost approximately $10,688.

Based on the April announcement of the suspension of 2020 data collection for the QIS that would normally have been submitted for PY 2021, CMS estimates that the burden for the 2020 year would be reduced from 48 hours to zero hours.) For all estimated 250 issuers combined, the burden to collect and report information for their quality improvement strategies for one year is estimated to take approximately 12,000 hours and cost approximately $1,336,000; and the burden to collect and report information for their quality improvement strategies for three years (2018-2020) is estimated to take approximately 24,000 hours and cost approximately $2,672,000.

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 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. To update the burden estimate for the renewal of this package, CMS escalated the expert-provided cost estimates using the Employment Cost Index for Escalation (as of December 2017) published by the Bureau of Labor Statistics.[6]

Although the escalation of wages and the increased fringe benefit rate of 100 percent results in a slightly higher cost per issuer, CMS has taken steps to significantly reduce the overall burden on issuers. Based on historical data, CMS reduced the estimate of QHP issuers submitting quality improvement strategies for 2019 through 2021 from 575 to 250 issuers, resulting in a decrease in overall burden. In the 2020 Plan Year, the total annual burden hours for completing the QIS form is estimated to be 12,000 hours. Due to a reduction in estimated numbers of QHP issuers for the 2020 Plan Year, CMS is calculating an estimated burden reduction of 15,600 hours annually. See Exhibit 2 for the effect of the reduced number of QHP issuers on overall annual burden reduction.

Exhibit 2: Annual Burden Reduction Due to Reduced Number of QHP Issuers

Source	No. of QHP Issuers	QIS per QHP Issuer	Estimated Burden Hours per Year	Total Cost per Issuer	Total Cost for all Issuers per Year
Estimated 2015 Plan Year Required Issuers	575	1	27,600	$3,372	$1,938,900
Estimated 2020 Plan Year Required Issuers	250	1	12,000	$5,344	$1,336,000
Total Reduction	-325	N/A	-15,600	+$1,972	-$602,900

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.

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https://www.bls.gov/web/eci/echistrynaics.pdf_

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.

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 sections 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 $343,414. 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

Revisions to the QIS form are minor, resulting in no change to the burden estimate of the hours needed to fill out the QIS form. However, due to a decrease in the estimated number of issuers making QIS submissions from 575 to 250, the overall burden has decreased from 27,600 hours per year to 12,000 hours per year. In calendar year 2020, there is an additional decrease in burden hours of 48 hours due to CMS' suspension of data collection resulting in an overall three year burden from 2018-2020 of 96 hours.

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 the document.