Quality Standards – Quality Improvement Strategy Supporting Statement

Supporting Statement for Information Collection: Quality Improvement Strategy Implementation Plan and Progress Report Form

A. Background

A Qualified Health Plan (QHP) issuer participating in a Marketplace 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 Affordable Care Act, to cover all of its QHPs. The QIS requirements apply to all issuers offering QHPs through the individual market 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 Marketplaces on a periodic basis.

All Marketplaces are required to evaluate quality improvement strategies for issuer applicants. State-based Marketplaces (SBMs) [1] will evaluate the strategies of the issuers applying to offer QHPs in their respective Marketplaces. The Centers for Medicare & Medicaid Services (CMS) will evaluate the strategies of issuers applying to offer QHPs in most Federally-facilitated Marketplaces (FFM).[2] In states performing plan management functions in State Partnership States (states performing plan management functions),[3] issuers applying to offer QHPs will undergo a joint review of their quality improvement strategies by the state and the FFM. CMS requests approval from the Office of Management and Budget (OMB) for the information collection associated with the QIS requirements.

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1 An SBM is a Marketplace model in which a state establishes and operates its own Health Insurance Marketplace, for both the individual and small group markets, pending approval by CMS.

2 FFMs are Marketplaces established and operated by CMS for individual and small group market coverage.

3 A state performing plan management functions in a State Partnership State (state performing plan management functions) is a hybrid Marketplace model in which a State operates plan management functions, while the federal government operates the remaining Marketplace functions. In the case of the QIS, a state performing plan management functions is a state that must evaluate the quality improvement strategies of the issuers in its state using the federal QIS evaluation methodology, but may establish its own approach to doing so (e.g., establish unique evaluation effort logistics).,).

B. Justification

1. Need and Legal Basis

The Affordable Care Act establishes requirements to support the delivery of quality health care coverage for health insurance issuers offering QHPs through the Marketplaces.[4] Section 1311(c)(1)(E) of the Affordable Care Act specifies that to be certified as a QHP for participation in a Marketplace, each health plan must implement a QIS. Section 1311(g)(1) of the Affordable Care Act, entitled "Rewarding Quality Through Market-Based Incentives," describes this strategy as a payment structure that provides 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 implementing activities to reduce health and health care disparities. Section 1311(g)(2) of the Affordable Care Act requires the Secretary to develop guidelines in consultation with health care quality experts and stakeholders, including periodic reporting of the activities that the QHP has conducted to implement a QIS, to the applicable Marketplace, as described in section 1311(g)(3). 45 C.F.R. § 155.200(d) directs Marketplaces 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 a Marketplace. The statutory QIS requirements extend to all Marketplace types, including the FFMs, states performing plan management functions, and SBMs. The requirements and standards that will be used for the FFMs provide the starting point for SBMs to build upon. SBMs will 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 Marketplaces.

In accordance with Section 1311(g) of the Affordable Care Act, CMS is establishing the QIS requirements. CMS requests OMB clearance for this Information Collection Request (ICR) so that CMS may collect the information needed to implement the QIS requirements and standards established in the HHS Notice of Benefit and Payment Parameters for 2016; Final Rule.

2. Information Users

QIS information will be collected from issuers on an annual basis beginning in calendar year 2016 for the 2017 coverage year. This will allow CMS to evaluate the compliance and adequacy of issuers' QIS implementation efforts, as required by Section 1311(c) of the Affordable Care Act. CMS will use issuers' validated information to evaluate issuers' QIS for compliance as a condition of certification.

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 issuers, if necessary, by email and telephone.

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

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 Marketplaces according to the Affordable Care Act.

7. Special Circumstances

Not applicable.

8. Federal Register Notice/Outside Consultation

CMS is working with a variety of experts to establish and operationalize 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 provides routine input on QIS technical and methodological issues to Booz Allen. The QIS TEP membership is composed of issuer representatives, Marketplace 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. CMS also conducted a pilot test consisting of two interviews with participating issuer organizations and an SBM, mock QIS Implementation Plan and Progress Report (formerly called the "QIS Plan Template and Reporting Template") submissions, and evaluations of the mock submissions. CMS held listening sessions with Marketplaces, issuers, and issuer associations. Finally, the QIS Technical Guidance and User Guide for the 2017 Coverage Year (Technical Guidance/User Guide) was distributed within CMS for review as part of the HHS document publication clearance process, with many CMS 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 QIS Implementation Plan and Progress Report form was available during a 30-day public comment period associated with the Paperwork Reduction Act (PRA). A total of two comment submissions were received about the QIS Implementation Plan and Progress Report form (form), both from issuer associations.

One commenter suggested removing Element 15 (*Current Payment Model(s) Description*), which requests issuer information related to the amount of overall provider payments tied to quality or value, because the element is outside the scope of Section 1311(g) of the Affordable Care Act. The other commenter cautioned against including Element 15 because there is no consistent methodology to measure the percentage of provider payments tied to quality or value.

Both commenters suggested that collection of data sources used to develop and monitor quality improvement strategies (e.g., medical records, claims files, surveys, etc.) in Element 16 (*Data Sources*) be removed. One commenter specified there could be wide variations in data sources across issuers, making the utility of collecting the information unclear.

One commenter asked for further explanation of the definition of "market-based incentives." This commenter also suggested that a QIS should not have to apply to a health plan's full enrollee population. Both commenters asked for additional clarification on CMS's definition of "reducing health and health disparities," and on the QIS reporting requirements, including how issuers should calculate their baseline results. One commenter also suggested allowing flexibility in measuring QIS progress and performance, and recommended removing the requirement to use clinical quality measures and performance targets to measure progress.

Both commenters asked for additional clarification on the changes issuers would be able to make to their quality improvement strategies and when these changes could be made during implementation. Both commenters also expressed the desire for flexibility in designing and implementing a QIS. Both commenters sought clarification on whether the QIS includes a public reporting aspect, and asked for consistency of public display across issuers and alignment with the Quality Rating System. One commenter also requested consistency in QIS requirements across Marketplace types.

One commenter suggested that the QIS requirements apply to all issuers, not only to issuers that have operated in the Marketplaces for two consecutive years, while the other commenter supported phasing in the QIS for new issuers. Finally, one commenter asked for trainings and resource materials to better educate issuers on the QIS reporting submission and evaluation processes.

CMS refined the Technical Guidance/User Guide to address some of these comments and further explain the QIS requirements during the initial years. CMS entities reviewed the Technical Guidance/User Guide as part of the HHS publication clearance process. As part of this review, they provided comments on the QIS requirements which subsequently led to changes to the QIS Implementation Plan and Progress Report form. The changes described below reflect both public comments and the Technical Guidance/User Guide clearance comments that resulted in changes to the form.

CMS clarified that payment model information collection, included under Element 15 (*Current Payment Model(s) Description*) should be based only on payments made to providers through their Marketplace product line. CMS also clarified that Element 15 reflects the goals of HHS' *Better, Smarter, Healthier* initiative, and that information collection is meant to promote transparency and track progress without discouraging innovation. In response to concerns about the relevancy and evaluation of Element 15, CMS clarified that the QIS and Element 15 were developed with flexibility to encourage issuer innovation and promote a culture of continuous quality improvement. CMS clarified that the purpose of collecting issuers' data sources (Element 16) is to promote transparency.

CMS added detail to the definition of "market-based incentive," and added information to support the inclusion of enrollee-facing incentives within this definition. CMS also clarified that issuers must have a QIS for each of their QHPs, but that the QIS does not have to cover all of the QHP's enrollees. CMS further clarified that issuers are encouraged to address and reduce health

and health care disparities via their QIS but are not required to do so. As a result, CMS removed criterion 22b and modified criterion 23d from the form. Related to this, CMS clarified that activities related to reducing health and health care disparities—such as data analysis, consumer engagement, navigation tools or cultural competency training—must be tied to a market-based incentive to comply with the QIS.

In the initial years of QIS implementation, CMS will not establish any standardized or uniform set of performance measures for inclusion in an issuer's QIS, and will not require issuers to select measures from any specific set of measures. Issuers will have broad flexibility in selecting the measures used to track progress related to their QIS. CMS encourages issuers to use national, state, or regional benchmarks when establishing their baseline and performance targets. CMS clarified that a QIS should incentivize quality, tying payments to measures of performance, when providers meet specific quality indicators.

CMS clarified that issuers will have the opportunity to make changes to the activities, goals, and/or quality measures as needed, on an annual basis, without creating a new QIS/submitting a new QIS Implementation Plan. Issuers will provide information on these modifications via the Progress Report section of the form, but do not have to wait until the submission of the form to implement these modifications. An issuer will have to submit a new QIS if: (1) the issuer changes the topic area and/or market-based incentive type or sub-type of its QIS; (2) if one or more performance targets are reached or changed ; (3) and/or, (4) if the QIS results in negative outcomes or unintended consequences. CMS clarified that issuers operating through a Marketplace that transitions from an SBM to an FFM will be considered to be continuing with an existing QIS during their first year in an FFM, unless they wish to submit a new QIS.

Issuers will have the flexibility to implement a strategy focusing on the issues of greatest importance to their markets and covered populations. CMS revised the Technical Guidance/User Guide to include language specifying that issuers offering Multi-State Plan (MSP) options should contact the Office of Personnel Management (OPM) to confirm the requirements and timing associated with QIS implementation. The QIS is designed to provide SBMs with flexibility to establish the timeline, format, validation, and other requirements related to the annual submission of QIS data by issuers that participate in their respective Marketplaces.

CMS believes that two years is an appropriate time period for issuers to understand their populations who have enrolled through Marketplaces, and develop relevant quality improvement strategies to meet the needs of that population. CMS is developing issuer training and additional resource materials to better prepare issuers and the Marketplaces for QIS implementation and evaluation.

9. Payment/Gift to Respondents

Not applicable.

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 a Marketplace in accordance with the proposed QIS Implementation Plan and Progress Report form, but not the burden of implementing a QIS.

Burden Estimate for 575 Issuers

The estimate assumes 575 issuers (all issuers in all Marketplaces, excluding Stand-Alone Dental Plans [SADPs]), and covers the annual costs for an issuer over a three-year period (2016-2018). The estimate assumes participation of all issuers in all Marketplace 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 575 issuers will complete and submit the necessary portions of the QIS Implementation Plan and Progress Report 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 the table.

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

Step #	Step Name	Average Hourly Labor Costs (Hourly Rate + 35% Fringe Benefits)	Hour Burden	Total Cost Burden (Per Issuer)
1	Gather Information	$67.78	41	$2,779
2	Develop Response and Submit Form	$84.71	7	$593
	Total		48	$3,372

For one issuer, the burden to collect and report information for its QIS for three years is estimated to take approximately 144 hours and cost approximately $10,116.

For all issuers combined, the burden to collect and report information for their quality improvement strategies for one year is estimated to take approximately 27,600 hours and cost approximately $1,938,900.

For all issuers combined, the burden to collect and report information for their quality improvement strategies for three years is estimated to take approximately 82,800 hours and cost approximately $5,816,700.

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 35% was applied to the hourly wage rates.

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

During the QHP Application Period, an issuer will submit information regarding its QIS to the Marketplaces via the Implementation Plan and Progress Report form. In the first year of participation, the issuer will submit a QIS Implementation Plan via the form that describes its quality improvement strategy or strategies for all its QHPs offered through the FFM, including QHPs offered in states performing plan management functions. The following year, and each year thereafter (until an issuer submits a QIS Implementation Plan for a new strategy), the issuer will submit a QIS Progress Report via the form, which describes implementation progress related to its QIS. The issuer will also 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 2 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 2. 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 Marketplace 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 Marketplaces. 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 a Marketplace. There will be up to three rounds of QIS review that will occur concurrently with the three rounds of QHP Application review (First Review, Second Review, and Final Review). An issuer whose initial QIS submission meets the requirements will not undergo second or final reviews. An issuer whose initial QIS submission

does not sufficiently meet the requirements during the review will need to resolve any issues, make clarifications, and re-submit a revised form during the next 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 such 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 required from issuers in revising and re-submitting a form is considered to be information that does not require OMB clearance.

This estimate also does not account for the burden incurred by SBMs 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 $378,068. This cost estimate reflects the costs associated with collecting information from issuers offering QHPs only in states operating as Federally-facilitated Marketplaces (FFMs) (which includes states performing plan management functions).

15. Explanation for Program Changes or Adjustments

This is a new information collection required by the Affordable Care Act.

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

Not applicable. CMS plans to include an OMB expiration date once assigned an OMB control number.

18. Certification Statement

There are no exceptions to the certification.