Supporting Statement – Quality Standards

A. Background

The HHS' goals for improving access to high-quality, affordable care, and supporting healthier people and communities, as described in the National Strategy for Quality Improvement in Health Care (National Quality Strategy)[1], continue to guide the establishment of quality standards for Exchanges and for Qualified Health Plans (QHP). HHS is requesting approval, by the Office of Management and Budget (OMB), for the revision associated with Part IV of this supporting statement which details the information collection associated with finalized Patient safety reporting standards for QHP issuers:

I. Implementation and reporting for the Quality Rating System (QRS);
II. Implementation and reporting for the Enrollee Satisfaction Survey (ESS);
III. Monitoring and appeals process for survey vendors; and
IV. Patient safety reporting standards for Qualified Health Plan (QHP) issuers.

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 Qualified Health Plans (QHPs) in Exchanges. Section 1311(c)(3) of the Affordable Care Act directs the Secretary to develop a system to rate QHPs on the basis of quality and price and requires Exchanges to display this quality rating information on their respective websites. Section 1311(c)(4) of the Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey (ESS) system to assess enrollee experience with each QHP (with more than 500 enrollees in the previous year) offered through an Exchange. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards beginning January 1, 2015.
This Information Collection Request (ICR) was approved under OMB Control Number 0938-1249 so that HHS may collect required information in order to implement the proposed quality standards outlined in §156.1105, §156.1110, §156.1120, §155.1125. The collection of information is necessary to provide adequate and timely health care quality information for consumers, regulators and Exchanges in the initial years of Exchange implementation. It is also necessary to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve the ESS vendor application. We revised this information collection to account for the associated burden of the finalized QHP issuer patient safety reporting standards from the HHS Notice of Benefit and Payment Parameters for 2017 (0938-AS57) published in the Federal Register on March 8, 2016.

2. Information Users

[1] See Report to Congress: National Strategy for Quality Improvement in Health Care available at http://www.healthcare.gov/law/resources/reports/quality03212011a.html.

I. Implementation and reporting for the Quality Rating System (QRS)

The QRS quality measure data will be collected from QHP issuers on an annual basis in order for HHS to be able to calculate scores and quality ratings for QHPs, as required by section 1311(c)(3) of the Affordable Care Act. We intend to have a beta testing period in 2015 to provide early feedback to Exchanges and QHP issuers and begin public reporting of quality rating information in 2016. This quality rating information will be displayed on Exchange websites for consumers to have QHP rating information including health care quality, health outcomes, consumer experience, accessibility of care and affordability of care, which is information that is essential to inform consumer choices and to perform certain required functions of an Exchange. HHS will use the validated data that is submitted by QHP issuers to calculate scores and ratings based on a standardized methodology which is currently being developed and finalized.

II. Implementation and reporting for the Enrollee Satisfaction Survey (ESS)

The information collection associated with implementation and reporting for the ESS, as proposed in §156.1125, includes the collection, validation and submission of ESS data on an annual basis. We intend to have a beta testing period in 2015 and begin public reporting of enrollee satisfaction survey results in 2016. The ESS, also known as the QHP enrollee experience survey, will provide member experience data which is a fundamental aspect of the overall quality of the QHP. The burden estimates and costs regarding survey respondents are already accounted for and described in the Federal Register Notice dated Nov. 1, 2013.[2] The ESS information submitted to HHS will be used for HHS to calculate ESS scores and benchmarks to send to Exchanges and to QHPs. In addition, a subset of the ESS scores will be used as part of the quality ratings for QHPs. ESS results will be displayed on Exchange websites to allow consumers to compare enrollee experience across QHPs.

III. Monitoring and appeals process for survey vendors

We propose to establish a monitoring and appeals process for HHS-approved ESS vendors in the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and 2016. Specifically, in §156.1105(d), we establish a process in which HHS will monitor approved vendors for ongoing compliance. HHS may require additional information from approved vendors to be submitted as needed and in order to ensure continued compliance with standards listed in §156.1105(b)(1) through (11). HHS will use this information to determine whether the ESS vendor should remain on the approved list and/or whether the submitted survey results may be ineligible to be included for ESS results. In §156.1105(e), we propose a process by which a survey vendor that was not approved by HHS could appeal HHS's determination. The vendor would submit documentation to demonstrate how the vendor meets the necessary standards to HHS for review. HHS will use this information to make a final approval determination of whether or not to list the vendor as an HHS-approved ESS vendor.

[2] Agency Information Collection Activities: Health Insurance Marketplace Consumer Experience Surveys: Enrollee Satisfaction Survey and Marketplace Survey Data Collection; Notice, 78 FR 65658 (Nov. 1, 2013).

IV. Patient safety reporting standards for QHP issuers.

We finalized amendments to QHP patient safety reporting standards in the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (81 FR 12203) , March, 2016. We finalized the documentation requirement in §156.1110(b) to require QHP issuers to collect and maintain information such as a hospital attestation or a copy of the current agreement to partner with a Patient Safety Organization (PSO), a Hospital Engagement Network, or a Quality Improvement Organization. The documentation should reflect implementation of PSO activities, such as PSOs and hospitals working together to collect, report and analyze patient safety events, and implementation of a comprehensive person-centered hospital discharge program to demonstrate compliance with the proposed requirements in §156.1110(a)(2)(i); or implementation of a patient safety initiative to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination to demonstrate compliance with the reasonable exception provision finalized in §156.1110(a)(2)(ii). An Exchange may request this information and may use the information as demonstration of compliance by QHP issuers with patient safety reporting standards outlined in §156.1110.

3. Use of Improved Information Technology and Burden Reduction

All information collected from QHP issuers for implementation and reporting of the QRS, ESS and patient safety standards will be submitted electronically. HHS staff will analyze the data electronically and communicate with issuers and State-based Exchanges, if necessary, by email and telephone. Information collected from survey vendors regarding the monitoring and appeals process will be electronic as well.

4. Efforts to Identify Duplication and Use of Similar Information

These are new quality reporting standards and programs created under the Affordable Care Act and the information to be collected has never been collected by the federal government for the use of providing quality ratings and ESS results for QHPs; for use in a monitoring and appeals processes for ESS vendors; and for patient safety reporting by QHPs. We acknowledge that similar information (i.e. quality measures and CCN data) is collected by CMS quality reporting programs including Medicare Star Ratings, Medicaid Adult Core Measures, Initial Children's Core Set, Medicare Part C&D programs; however, we believe that this information collection is not duplicative since it will provide necessary data for the new Exchange market while also aligning with standards from established programs to minimize burden and costs for stakeholders.

5. Impact on Small Businesses or Other Small Entities

No impact on small business.

6. Consequences of Collecting the Information Less Frequently

If HHS does not collect the QRS and ESS information on an annual basis, HHS will be unable to calculate scores and ratings for QHPs as required by section 1311(c)(3) and (c)(4) of the Affordable Care Act. In addition, HHS will be unable to send the appropriate QHP quality information to Exchanges for display on their websites as also required. If HHS does not collect information to monitor ESS vendors then there may be increased risk of noncompliance by vendors.

7. Special Circumstances

Not applicable.

8. Federal Register Notice/Outside Consultation

CMS provided an opportunity for the public to comment for 60-days through the Notice of Proposed Rulemaking (80 FR 75488, December 2, 2015). No comments were received.

A 30-day comment solicitation published on March 8, 2016 at 81 FR 12204, giving the public 30-days to comment.

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. Estimates of Annualized Burden Hours (Total Hours & Wages)

I. Implementation and reporting for the Quality Rating System (QRS)

The burden estimate details the costs associated with QRS measure data collection, validation, and submission to CMS for a QHP issuer (issuer) operating in the Health Insurance Marketplace. The estimate assumes 575 issuers and covers the annual costs for an issuer over a three-year period (2015-2017). The estimate relies on the assumption that each issuer will report the QRS measure set only.

Though the QRS measure set consists of 43 measures, this burden estimate only considers the level of effort associated with 31 measures that specify data collection using administrative data sources and/or medical records. The burden estimate for survey respondents for the remaining 12 QRS measure set survey measures was accounted for in a previous Federal Register notice related to the ESS or QHP Enrollee Experience Survey[3]. See Exhibit 1 for the QRS measure set attributes considered in estimating the burden of QRS measure data collection. The original burden estimates were made based on the draft QRS measure set released in the FRN published November 3, 2013.[4]

In response to the feedback received during the public comment period, CMS reviewed the assumptions and data inputs used to create the QRS burden estimates. Since publication of the ICR, the QRS measure set had been revised and was published soon after the Final Rule was issued.[5] Due to the changes in the QRS measure set, CMS revised the burden estimate to reflect the final 2015 QRS beta test measure set. Exhibit 1 shows the change in key measure set attributes between the draft QRS measure set and the final 2015 beta test QRS measure set.

Exhibit 1. QRS Measure Set Attributes Related to Data Collection

Attribute Description	Draft QRS Measure Set	Final 2015 QRS Beta Test Measure Set
Subset of QRS Measures Accounted for In Burden Estimate Subset of QRS measure set that specify data collection using administrative and/or medical record data sources	29	31
Administrative Measures	20	18

[3] Agency Information Collection Activities: Health Insurance Marketplace Consumer Experience Surveys: Enrollee Satisfaction Survey and Marketplace Survey Data Collection; Notice, 78 FR 65658 (Nov. 1, 2013).
[4] https://www.federalregister.gov/articles/2013/11/19/2013-27649/patient-protection-and-affordable-care-act-exchanges-and-qualified-health-plans-quality-rating
[5] Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond Final Rule, 79 FR 30352 (May 27, 2014).

Attribute Description	Draft QRS Measure Set	Final 2015 QRS Beta Test Measure Set
Measures that specify the use of claims or other administrative source data		
Hybrid Measures that Require a Unique Sample Measures that specify the use of medical record data to supplement administrative data	9	10*
Average # of Medical Records Reviewed for Each Hybrid Measure that Requires a Unique Sample The number of medical records, on average, that an issuer reviews to determine measure compliance	335	330

*Though there are 13 hybrid measures in the final QRS measure set only 10 require a unique sample.

CMS conducted interviews with issuers that had experience with performance measures data collection and other technical experts to confirm the data collection process and the associated burden. The following data collection process steps served as the basis for estimating labor hours:

- Preparation of IT Systems for Data Collection
- Data Collection – Administrative Method
- Data Collection – Medical Record Method
- Data Aggregation and Quality Assurance
- Data Validation
- Data Submission

The estimate assumes that issuers will report QRS measure data to CMS by product type (HMO, POS, PPO, and/or EPO). Thus, the estimate uses a weighting factor to represent the workload for issuers with multiple product types[6].

Exhibit 2 includes the labor categories and wage rates used to derive the burden estimate. The categories are based on those cited by the Department of Labor, Bureau of Labor Statistics (BLS). A sample of issuers informed modifications to the function descriptions associated with each category so that they aligned more with performance measures data collection. Wages, fringe benefits, and overhead costs are based on BLS wage statistics as of May 2012. The 75th percentile is used for hourly wages in order to generate a conservative burden estimate. This burden estimate represents the average, annual cost for an issuer over the 2015-2017 QRS measure reporting period. Since wage, fringe benefits, and overhead cost data were taken from 2012 BLS reports (the most recent data available), the model includes a wage growth factor to account for the anticipated changes in total compensation. The wage growth factor was determined by averaging annual growth rates of

[6] The estimate uses a weight of 1.25 that equates to the average number of product types per issuer in aggregate. This is based on CMS data received 11/01/13.

total compensation between 2004 Quarter 2 to 2013 Quarter 2 supplied by BLS.

Due to the increase in overall measures by 7%, including the addition of one hybrid measure that requires a unique sample, CMS revised the burden estimate accordingly. Data collection for hybrid measures requires a greater level of effort than administrative measures. Considering these changes, CMS increased labor hours for QHP issuer staff by 11%, which resulted in an approximate 10% increase (9.7%) in total cost per QHP issuer. The revised annual labor hours and associated costs are reflected in Exhibit 2.

Exhibit 2. Labor Categories and Wage Rates

Labor Category	Function	Hourly Wage[7]	Hourly Wage Rate for Period 2015-2017[8]	Total Hourly Wage Rate for Period 2015-2017[9]
General and Operations Manager	Formulate policies, manage daily operations, and plan the use of materials and human resources.	$69.81	$76.41	$108.69
Computer Programmer	Modify and test code. Use statistical methods to organize, interpret, QA, and summarize data.	$45.26	$49.54	$70.46
Business Operations Specialist, Other	Train reviewers. Review and over-read charts for quality assurance.	$41.81	$45.76	$65.09
Registered Nurse	Review medical records for measure data collection.	$37.84	$41.42	$58.91
Medical Records and	Compile, process, review, and maintain	$21.33	$23.35	$33.21

[7] 75th percentile is referenced. Data source: http://www.bls.gov/oes/current/oes_stru.htm
[8] Hourly wage + wage growth factor of 2.28%. Wage growth factor data source: BLS 2004 Q2 to 2013 Q2 - http://www.bls.gov/ncs/ect/data.htm
[9] Hourly wage rate for period + overhead & fringe benefit rate of 42.24%. Overhead & fringe benefit data source: BLS 2012 Q2 - http://www.bls.gov/ncs/ect/data.htm

Labor Category	Function	Hourly Wage[7]	Hourly Wage Rate for Period 2015-2017[8]	Total Hourly Wage Rate for Period 2015-2017[9]
Health Information Analyst	medical records and patient information.			

The estimated annual cost burden for issuers is based on an average of estimates provided by a sample of issuers. The sample was comprised of issuers that have performance measures data collection experience, which represents the majority of issuers that will report QRS measures data. Each issuer estimated labor hours for each applicable labor category involved with the data collection process. Estimates assumed that issuers will follow usual practices of contracting with a third-party for data validation and using existing program data submission tools with which they are familiar. Exhibit 3 displays the estimated annual cost burden for a single issuer and includes the labor hours per labor category (for internal staff).

Exhibit 3. Annual Estimated Cost Burden for One Issuer

	Internal Staff					Third-Party Validator
	General and Operations Manager	Computer Programmer	Business Operations Specialist, Other	Registered Nurse	Medical Records and Health Information Analyst	
Total Hours by Labor Category	206	335	145	892	252	
Total Hourly Wage Rate	$108.69	$70.46	$65.09	$58.91	$33.21	
Subtotal Cost	$22,390	$23,604	$9,438	$52,548	$8,369	$12,500

	Internal Staff	Third-Party Validator
Total Cost	$128,849	

For one QHP issuer, the burden to collect and report data for the QRS is estimated to take approximately 1830 hours and $128,849 each year. Therefore, the total annual hour and cost burden for 575 issuers is 1,052,250 hours and $74,088,175.

II. Implementation and reporting for the Enrollee Satisfaction Survey (ESS)

The estimated annual hour and cost burden for an issuer to collect, validate, and submit data for the ESS includes contracting with an HHS-approved ESS vendor, contracting with an auditor, generating the sampling frame data, reviewing survey materials, authorizing its contracted survey vendor, and signing off on the data to be submitted to HHS.

The ESS is largely based on the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) 5.0 Health Plan Survey which the majority of issuers already have experience with. Therefore, the burden estimates are similar to established CAHPS survey estimates for health plans such as those approved under OMB Control Number 0938-0732 (Medicare CAHPS surveys). **It is estimated that an issuer takes an average of 54 hours a year for the ESS. For the estimated 575 QHP issuers, the total annual burden is 31,050 hours. It is estimated that it costs an issuer $1349.60 each year for a total annual cost of $776,020 for 575 issuers.**

Exhibit 6. Annual Estimated Hour and Cost Burden for QHP Issuers and ESS

Issuer Activity	Number of Respondents	Hours per response	Total Burden Hours	Average Hourly Wage Rate	Total Cost Burden
Contracting with HHS-approved ESS vendor	575	8	4600	$24.10	$110,860
Contracting with auditor	575	8	4600	$24.10	$110,860
Generating sampling frame	575	32	18,400	$24.10	$443,440
Reviewing survey materials	575	4	3450	$24.10	$83,145

Issuer Activity	Number of Respondents	Hours per response	Total Burden Hours	Average Hourly Wage Rate	Total Cost Burden
Authorizing survey vendor and signing off on data to be submitted	575	2	1150	$24.10	$27,715
Total		54	31,050		$776,020

III. Monitoring and appeals process for survey vendors

The estimated annual hour and cost burden for a survey vendor to provide information for HHS to determine continued compliance with approval criteria and ESS vendor minimum business requirements is approximately 40 hours and $964 for an estimated 40 vendors. It is estimated that only five vendors may file an appeal each year if not approved by HHS to be an ESS vendor. The annual hour and cost burden for those five vendors filing an appeal is estimated to be 5 hours and $120.50. **Therefore, the total annual estimated hour and cost burden for vendor monitoring and appeals are 45 hours and $1084.50.**

Exhibit 7. Annual Estimated Hour and Cost Burden for Vendor Monitoring and Appeals

Vendor Activity	Number of Respondents	Hours per response	Total Burden Hours	Average Hourly Wage Rate	Total Cost Burden
Compliance with monitoring	40	1	40	$24.10	$964.00
Filing an appeal	5	1	5	$24.10	$120.50
Total	45		45		$1084.5

IV. Patient Safety Reporting Standards for QHP Issuers

In the HHS 2017 Payment Notice final rule[10], we describe the information collection, recordkeeping, and disclosure requirements that a QHP issuer must meet to demonstrate compliance with the patient safety standards outlined in §156.1110. The burden estimate associated with these standards includes the time and effort required for QHP issuers to maintain and submit information such as a hospital attestation or a copy of the current agreement to partner with a PSO, a Hospital Engagement Network, or a Quality Improvement Organization, to the Exchange that demonstrates that each of its contracted hospitals with greater than 50 beds meets the patient safety standards in §156.1110(a)(2) for plan years beginning on or after January 1, 2017. We expect QHP issuers to already be collecting network provider information which is accounted for in the Supporting Statement associated with OMB Control Number 0938-1156. There is a wide range of numbers of relevant hospitals with greater than 50 beds across states from only one in some states to more than 300 hospitals in other states. We estimate a total of 575 QHP issuers, offering 15 plans as potential QHPs, would each take approximately an average of 3 hours to collect, maintain and submit applicable hospital agreements or information as finalized in §156.1110 for their QHPs. At an hourly billing rate of $91.31, we estimate the total annual cost for a QHP issuer to be $273.93. **Therefore, we estimate the total annual cost and annual burden to be $157,510and 1725 hours.**

Exhibit 8. Annual Estimated Hour and Cost Burden for QHP Issuer Patient Safety Reporting

Activity	Number of Respondents	Hours per response	Total Burden Hours	Average Hourly Wage Rate	Total Cost Burden
QHP issuers collect and maintain information such as applicable hospital agreements	575	2	575	$91.31	$105,007
QHP issuers submit this data to HHS and an Exchange	575	1	575	$91.31	$52,503
Total		3	1725		$157,510

[10] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Final Rule, 81 FR 12203 (March 8, 2016).

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers /Capital Costs

It is anticipated that capital costs would be incurred in the initial year(s) by issuers with limited experience in quality measure collection and submission as they develop their data collection systems and processes. These issuers will need to purchase and install software for QRS measure data collection. The anticipated cost for this purchase and installation is an estimated cost of $80,000. These issuers would also incur an additional $10,000 cost for third-party validation since validators may initially set higher fees for these issuers, given the increased resources needed to validate new systems and processes. Capital costs also include annual third-party validation costs which are estimated to be $12,500 for issuers. Issuers would also have to contract with an ESS vendor which is estimated to be approximately $16,000 annually. We estimate that these vendor contracting costs are conservative since issuers already contract with survey vendors to administer other similar CAHPS surveys and may not have to contract with additional new vendors for the ESS.

14. Annualized Cost to Federal Government

We estimate that the operations, maintenance and data collection costs associated with this information collection to the Federal government include contract costs for the QRS measure collection and reporting and the time and cost for one GS-level 13, one GS-level 14 and one GS-level 15 for data processing, managerial review and oversight. The calculations for federal employees' hourly salary are obtained from the OPM website, with an additional 35% to account for fringe benefits.

Task	Estimated Cost
Data Processing, Managerial Review, and Oversight	
1 GS-13, Step 1: $46.98 X 20 hrs	$940
1 GS-14, Step 1: $55.34 X 20 hrs	$1107
1 GS-15, Step 1: $65.31 X 5 hrs	$327
QRS measure collection and reporting	$898,969
ESS data collection	Already accounted for in OMB Control #0938-1221
Total Costs to Government	**$901,343**

15. Changes to Burden

This is an increase to the burden hour estimates approved in OMB Control Number 0938-1249. The newly established QHP patient safety standards would result in an annual estimated increase of 600 hours (1750-1150 hours) and $68,960 ($157,510-$88,550) for QHP issuers.

16. Publication/Tabulation Dates

Using the data collected for the QRS, HHS intends to calculate ratings associated with the QRS according to a standard rating methodology. We intend to have a 2015 beta testing period and

HHS proposes to direct Marketplaces to annually display the quality rating information on their websites beginning for the 2016 open enrollment period.

The publication activities for the ESS are already addressed in the Supporting Statement associated with OCN #0938-1221. We do not intend to publish any data associated with the monitoring and appeals process for survey vendors and for QHP patient safety reporting standards.

17. Expiration Date

Not applicable. We plan to include an OMB expiration date and the OMB control number on data collection instruments.

17. Certification Statement

There are no exceptions to the certification.