

**Supporting Statement – Part A**  
Application To Be a Qualified Entity to Receive Medicare Data for Performance Measurement /  
Reapplication / Annual Report Worksheet  
(CMS-10394; (OMB) 0938-1144)

I. Background

Section 10332 of the Patient Protection and Affordable Care Act (ACA) requires the Secretary to make standardized extracts of Medicare claims data under Parts A, B, and D available to “qualified entities” (QEs) for evaluating performance of providers of services and suppliers. The statute provides the Secretary with discretion to establish criteria determining whether an entity qualifies to use claims data to evaluate the performance of providers of services and suppliers. After consideration of comments from a wide variety of stakeholders during the public comment period, CMS established “Medicare Program; Availability of Medicare Data for Performance Measurement” (hereinafter called the Final Rule and referred to as the QE Program) published in the Federal Register on December 07, 2011 (42 CFR, Part 401, Subpart G). To implement the requirements outlined in the legislation, CMS established the Qualified Entity Certification Program (QECF) to evaluate an organization’s eligibility across three areas: (1) organizational and governance capabilities, (2) addition of claims data from other sources (as required in the statute), and (3) data privacy and security.

QE certification lasts for 3 years. Organizations that are interested in remaining in the QE Program must submit a Reapplication that is reviewed and approved by QECF. In addition, each year QEs must submit an annual report to QECF that provides information required by statute. During this update to the QECF PRA Package, CMS-10394, OMB 0938-1144 will be combined with CMS-10589 OMB 0938-1309 to create one QECF PRA Package that includes the QECF Application, QECF Reapplication, and QECF Annual Report Worksheet (ARW). These changes also include an addition of Data Security Audits to the Program and the Public Reporting Submission Tool to collect publicly reported information. With the combination of the packages and the additional work, we are requesting a 4,350 total hour decrease and \$622,216 increase in total cost over the 3-year period.

CMS is requesting a Revision type of OMB approval as a result of the above-mentioned updates.

II. Justification

1. Need and Legal Basis

The Patient Protection and Affordable Care Act (ACA) was enacted on March 23, 2010 (Pub. L. 111-148). ACA amends Section 1874 of the Social Security Act by adding a new subsection (e) to make standardized extracts of Medicare claims data under Parts A, B, and D available to QEs to evaluate the performance of providers of services and suppliers. This is the Application, Reapplication, and ARW which provides CMS with the information it needs to determine whether an organization earns approval and continues as a QE.

2. Information Users

CMS uses the information from the collection to determine whether an organization meets and continues to meet the criteria required to be considered a QE to receive Medicare claims data under ACA Section 10332. CMS evaluates the organization’s eligibility in terms of organizational and governance capabilities, addition of claims data from other sources, and data privacy and security.

### 3. Use of Information Technology

To assess an organization's compliance with QE eligibility requirements, QECF implements a phased application process. In addition, QE certification is valid for 3 years, and QEs must reapply at least 6 months prior to the 3-year certification expiration to ensure continued participation in the QE Program. During Reapplication, a QE submits documentation on any changes to ensure continued compliance with QECF requirements. To access the online Application, Reapplication, and ARW submission systems, a QE must register. Once they submit a registration form and QECF verifies it, QECF grants access to the secure QECF Application, Reapplication, or ARW via a Salesforce customer relationship management (CRM) system. Salesforce CRM is hosted in the Salesforce Government Cloud. QECF CRM access credentials include a unique user identifier (ID), password, and secure web uniform resource locator (URL). This user profile provides the applicant with access to the online application form, documentation library, frequently asked questions (FAQs), and other essential QECF resources. When an applicant is ready to submit an Application, Reapplication, or ARW for review, they simply click Submit. At that time, QECF validates the Application, Reapplication, or ARW for completeness. If found complete, QECF and CMS review commences. Organizations submit the Application, Reapplication, and ARW by an online form. In addition, on an as-needed basis, QEs authorized to provide QE data to a third-party organization must develop and manage a QE DUA with the third-party organization.

### 4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

### 5. Small Businesses

No special consideration is given to small businesses. The same information is needed to assess the qualifications of all organizations.

### 6. Less Frequent Collection

Data are collected once at the time of Application for each phase, Reapplication, DUA, and ARW submission. If this information was not collected or collected less frequently, CMS would not have evidence of Program participants meeting eligibility criteria for QEs under 42 CFR § 401.705 placing the privacy and security of Medicare beneficiary claims data at risk.

### 7. Special Circumstances

Some of the information QECF gathers as part of this data collection may be proprietary and confidential (e.g., financial statements, data flow diagrams, data security policies and procedures, and methodologies to develop and calculate non-standard measures). The contractor holds all information in this data collection strictly confidential and uses it only for the purpose of QECF. Access to information is restricted, and only those who are charged with reviewing the information for the purposes of certification or the oversight of such reviews, have access to the information. QECF uses information only for purposes of certification and do not make it available or disclosed outside the scope of the certification process unless appropriately authorized by "48 CFR § 352.224-71 - Confidential Information" terms and conditions in the government's contract with the data collection contractor.

### 8. Federal Register/Outsider Consultation

The 60-day federal register notice published on 01/29/2024 (89 FR 5548).

No comments received during the 60-day comment period.

The 30-day federal register notice published on 04/08/2024 (89 FR 89 FR 24480).

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents. This collection is to establish qualifications to use claims data to evaluate the performance of providers of services and suppliers.

10. Confidentiality

QECF pledges privacy to the extent allowed by law. The Application, Reapplication, and ARW are secure. QECF does not disclose proprietary data or information outside the Government and QECF does not duplicate, use, or disclose – in whole or in part – for any purpose other than to evaluate the Application, Reapplication, or ARW. QECF safeguards files containing submissions or information from these forms in accordance with Departmental standards and National Institute of Standards and Technology (NIST) Special Publication 800-53, Recommended Security Controls for Federal Information Systems and Organizations which limits access to only authorized personnel. The safeguards provide a level of security as required by OMB Circular No. A-130 (revised), Appendix III – Security of Federal Automated Information Systems.

11. Sensitive Questions

No sensitive questions are part of this information collection.

12. Burden Estimates (Hours and Wages)

To date, there are 40 QEs, comprising for-profit and not-for-profit organizations. Going forward, QECF anticipates a continuing increase in applications from healthcare analytic and technology companies given the expanded uses of the Medicare data afforded by Section 105 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2016. QECF also anticipates that provider network companies and other CMS-approved Qualified Clinical Data Registries will continue applying to the Program. QECF examined available information related to these entities to inform assumptions.

QECF estimates that the average response time to complete all phases of the Application (over a multiyear period), Reapplication, three ARWs, and as-needed DUA is 528 hours and includes a mix of staff from the following occupations: social scientists, information security analysts, legal staff, and executives. As described in Table 1, in a 3-year period a QE could complete Phase Application, a Reapplication, and three ARWs. Table 1 details the data collections and the number of responses we estimate for each over the next 3 years. QECF bases the time estimate for Application, Reapplication, as-needed DUA, and ARW preparation on the professional judgment of staff members at CMS and the QECF implementation support contractor.

**Table 1: QE Data Collections, Burden Estimates, and Frequency**

<b>QE Data Collections</b>	<b>Hours by Collection Activity</b>	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>3-Year Total Collections</b>	<b>3-Year Total Hours</b>
QE Applications	424	10	10	10	30	12,720
Reapplications	20	15	15	15	45	900
ARWs*	28*	40	45	50	135	3,780*

Totals	NA	NA	NA	NA	210	17,400
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\*The burden associated with the development and administration of QE DUAs, as may be needed by QEs in their interactions with authorized users, is incorporated into this data collection line item. This activity accounts for 8 hours per collection – for a total of 1,080 over 3 years.

To derive average costs, QECF used data from the U.S. Bureau of Labor Statistics May 2022 National Occupation Employment and Wage Estimates. Table 2 presents the mean hourly wage, cost of fringe benefits, and adjusted hourly rate.

**Table 2: U.S. Bureau of Labor Statistics Hourly Rates**

Occupation	2022 Hourly Rate	Fringe Estimate (100% hourly rate)	Total
Social Scientist	\$45.56	\$45.56	\$91.12
Information Security Analyst	\$57.63	\$57.63	\$115.26
Chief Executive	\$118.48	\$118.48	\$236.96
Legal Staff	\$78.74	\$78.74	\$157.48

Table 3 presents the estimated 3-year request for all QEs to complete Application, Reapplication, DUA, and ARW data collections to the public.

**Table 3: 3-Year Burden Estimate to the Public for New Consolidated Package**

Occupation	2022 Hourly Cost	Hours per Year	Total 3-Year Hours	3-Year Cost
Social Scientist	\$90.92	2,800	8,400	\$765,408
Information Security Analyst	\$115.26	1,945	5,835	\$672,542
Executive	\$236.96	695	2,085	\$494,062
Legal Staff	\$157.48	360	1,080	\$170,078
<b>Total to the Public</b>	<b>NA</b>	<b>5,800</b>	<b>17,400</b>	<b>\$2,102,090</b>

### 13. Capital Costs

There are no capital costs associated with preparing the Application, Reapplication, DUA, and ARW.

### 14. Cost to Federal Government

Annual cost to the government for this data collection is estimated at \$367,776. This estimate is calculated by summing the cost of one GS-13 (Step 4) with a fully loaded salary of \$186,000 and the QECF contract's cost for tasks related to data collection of \$181,776.

#### 15. Changes to Burden

The changes to burden reflected in this continuation of 0938-1144 are the result of an increase to accommodate new information collected through the QECF Data Security Audit to address concerns about data security and the storage and uses of the government data made available through the QE Program and the addition of the Public Reporting Submission Form. In addition, the increase in number of responses reflects the inclusion of collection activities previously authorized under OMB 0938-1309 and growth in the number of participants in the QE Program.

Decreases in the levels of burden are the result of changes in estimates for activities under the 0938-1309 prior package. Decreases in burden are the result of: (1) more efficient collection of ARW information through the online QECF CRM, (2) pre-populating several fields which previously had to be entered with each submission, and (3) adjusting the ARW data requested (and our estimate to match each respondent's phase on the Program; not seeking responses for non-applicable items in our data collections. The level of burden approved under the prior 0938-1309 package was notably higher. For example, in the prior package, the 3-year burden under 0938-1309 for the ARW and DUA was estimated at 10,350 hours. In this package, for those same activities we are requesting 7,560 hours. In addition to changes to burden, our new request also reflects an increase in the number of collections fueled by the growth of the QE Program. For example, under the prior 0938-1309 package ARW/DUA collection activities accounted for 45 collections. Our new request seeks authorization for 135 collections. In total we were approved for a combined 75 collections under prior 0938-1144 and 0938-1309 packages while in this package, for those same activities, we are requesting 210 collections (3-years).

Overall, the impact of the decrease in combined burden coupled with an increase in the number of collections drives the decrease in cost per collection reflected in Table 3.

In summary, changes to burden and cost displayed in Table 4 are driven by (1) an increase in the number of organizations participating in the QE Program and thus the number of responses/units; (2) activation of Data Security Audits for participants with Medicare data; (3) the creation of the Public Reporting Submission Tool, (4) efficiencies achieved in ARW collections, and (5) increases in the cost per hour of labor.

The hours per collection is calculated by totaling the total hours requested and dividing by the number of collection activities over the 3-year period.

**Table 4: Combined Changes to Burden and Cost**

<b>Item</b>	<b>Prior Package: 0938-1144</b>	<b>Prior Package: 0938-1309</b>	<b>Prior Packages Combined</b>	<b>New Request</b>	<b>Change</b>
3-Year # of Collections	30	45	75	210	135
3-Year Total Hours	11,400	10,350	21,750	17,400	-4,350
3-Year Total Cost	\$1,178,790	\$301,084	\$1,479,874	\$3,205,418	\$1,725,544

16. Publication/Tabulation Updates

There are no publication/tabulation dates associated with this collection.

17. Expiration Date

We plan to display the PRA number and expiration date on the “Instructions” tabs of the Data Source Attestation, the Data Security Review, the Measure Information Workbook, the ARW, and the landing page for Reapplication.

18. Certification Statement

There are no exceptions to the certification statement.