

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.

This collection covers the application through which organizations provide information to CMS to determine whether they will be approved as a qualified entity. This collection also covers the triennial re-application through which organizations provide information to CMS to determine whether they are approved to continue as a qualified entity and the QECF Annual Report Worksheet (ARW). CMS is requesting minor revisions to existing instruments in this package (0938-1144).

CMS does not anticipate that there will be a change in the burden due to these minor revisions. CMS estimates that only change in cost burden is due to increases in labor rates.

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 (91 FR 13029) published on 3/18/2026.

There were two comments on the PRA package. The response to comment document is attached as a supplemental document. There were no changes made to the collection.

The 30-day Federal Register Notice (91 FR 44849) published in the Federal Register 7/17/2026.

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

QE Data Collections	Hours by Collection Activity	Year 1	Year 2	Year 3	3-Year Total Collections	3-Year Total Hours
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

*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 2025 National Occupation Employment and Wage Estimates.

<https://data.bls.gov/oes/#!/area/0000000/2025>

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	2025 Hourly Rate	Fringe Estimate (100% hourly rate)	Total
Social Scientist (19-3000)	\$51.08	\$51.08	\$102.16
Information Security Analyst (15-1212)	\$63.71	\$63.71	\$127.42

Chief Executive (11-1011)	\$129.63.48	\$129.63	\$259.26
Legal Staff (23-1011)	\$89.35.74	\$89.35	\$178.7

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	2025 Hourly Cost	Hours per Year	Total 3-Year Hours	3-Year Cost
Social Scientist	\$102.16	2,800	8,400	\$858,144
Information Security Analyst	\$127.42	1,945	5,835	\$743,495.70
Executive	\$259.26	695	2,085	\$540,557.10
Legal Staff	\$178.70	360	1,080	\$192,996
Total to the Public	NA	5,800	17,400	\$2,335,192.80

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 \$466,776. This estimate is calculated by summing the cost of one GS-13 (Step 5) with a fully loaded salary of \$285,000 and the QECF contract's cost for tasks related to data collection of \$181,776.

15. Changes to Burden

There was an increase in burden for the cost to the public and to the federal government. These increases are due to increases in labor rates. The cost to the public increased by 233,102.8 and the

cost to the federal government increased by 99,000. The total increase in burden was 332,102.8. CMS does not anticipate that there will be a change in the burden due to the minor revisions to the instruments. CMS made minor revisions to existing instruments to better align with program requirements and better organize and streamline the collection of information.

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.