

**Supporting Statement – Part A**  
**Reapplication Submission Requirement for Qualified Entities under ACA Section 10332**

**A. 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” for the evaluation of the performance of providers of services and suppliers. The statute provides the Secretary with discretion to establish criteria to determine whether an entity is qualified to use claims data to evaluate the performance of providers of services and suppliers. Under 42 CFR 401.709(f), qualified entity certification lasts three years. Six months prior to the end of the three year approval period, a qualified entity that is eligible to continue in the program must re-apply. This is the reapplication that is required to maintain qualified entity certification.

**B. 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 qualified entities to evaluate the performance of providers of services and suppliers. This is the reapplication needed for organizations to maintain their status as a qualified entity required under 42 CFR 401.709(f).

2. Information Users

The information from the collection will be used by CMS to determine whether an organization meets the criteria required to be considered a qualified entity to receive Medicare claims data under ACA Section 10332. CMS will evaluate 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

The initial plan is to use electronic submission. We anticipate that all applications will be submitted by this means.

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 considerations are 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 reapplication. Entities that are initially approved need to reapply for qualified entity status at least six months prior to the end of their three-year approval period. Recertification after three years is needed to ensure that appropriate standards of organizational capacity, governance, data security and confidentiality are maintained.

7. Special Circumstances

No special circumstances.

8. Federal Register/Outside Consultation

Public input on how CMS might implement the requirements of ACA section 10332 was sought in an Open Door Forum listening session on September 20, 2010. Using this input, a Notice of Proposed Rule Making (NPRM) was drafted and published in the Federal Register, which proposed to amend 42 CFR, Chapter IV, Part 401 by adding Subpart G – Availability of Medicare Data for Performance Measurement [76 Fed. Reg. 33566-33588 (June 8, 2011)]. The NPRM included a description of the proposed information collection requirements. CMS received no specific comments on the proposed information collection requirements.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

We pledge privacy to the extent allowed by law. The applications will be kept secure. No proprietary data or information will be disclosed outside the Government and will not be duplicated, used, or disclosed – in whole or in part – for any purpose other than to evaluate the application. Files containing the applications or information from these forms will be safeguarded 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 shall provide a level of security as required by Office of Management and Budget (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. Burdens Estimates (Hours & Wages)

We estimate that 10 organizations will submit reapplications in the next three years to maintain their QE status. In estimating qualified entity impacts, we used average hourly labor costs in two labor categories reported by the Bureau of Labor Statistics (BLS) at <http://data.bls.gov/pdq/querytool.jsp?survey=ce>. We used the latest available average hourly earnings rate (February 2015) and added 100 percent for overhead and fringe benefit costs. These rates follow:

Labor Category	2015 hourly wage rate	Overhead/ fringe (33%)	Total hourly cost
Professional & technical services	\$38.50	\$38.50	\$77.04
Legal services	\$40.15	\$40.15	\$80.30

Organizations initially approved to be qualified entities will need to re-apply every three years. We estimate that the re-application will require a total of 120 hours of effort, requiring a combination of staff in the professional and technical services legal labor categories, as follows:

Activity	Total Hours	Hourly Cost	Cost per Applicant	Number of Applicants	Total Costs
<b>Prepare draft application</b>	86	\$77.04	\$4,403.20		
<b>Legal Review</b>	10	\$53.40	\$534.00		
<b>Revisions to draft application</b>	14	\$77.04	\$716.80		
<b>Senior management review and sign-off</b>	10	\$77.04	\$512.00		
<b>Total</b>	120		\$6,166.00	10	\$61,660.00

From this, we estimate that the cost per organization for re-applying to be a qualified entity will

be \$6,166.00, and we estimate that 10 organizations will re-apply. The total hour burden for re-applying will be 1,200 hours and the total cost will be \$61,660.00.

Based on the information listed above, the annual burden associated with these information collection requirements is 400 hours.

1,200 hours divided by 3 years = 400 hours

Additionally, the annual average costs is estimated at \$20,553.33.

\$61,660.00 costs divided by 3 years = \$20,553.33.

13. Capital Costs

There are no capital costs associated with preparing the application to be a qualified entity.

14. Cost to Federal Government

It is estimated that CMS costs for managing the information collection will include one-eighth full time equivalent at the GS-13 step 4 level with an annual fully loaded salary of \$99,905, and \$55,000 in contractor support, for a total of \$67,488.

15. Changes to Burden

This is a new collection so there is no change in burden.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will display the expiration date as indicated. The information can be found at the bottom of the cover page for the application.

18. Certification Statement

There are no exceptions to the certification statement.