

Supporting Statement – Part A
Application To Be a Qualified Entity to Receive Medicare Data for Performance
Measurement (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. We are proposing at section CFR 401.703 to evaluate an organization’s eligibility across three areas: organizational and governance capabilities, addition of claims data from other sources (as required in the statute), and data privacy and security. This is the application through which organizations will provide information to CMS to determine whether they will be approved as a qualified entity.

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 application needed to determine an organization’s eligibility as a qualified entity.

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 application. Entities that are initially approved would need to reapply for qualified entity status after two years. Recertification after two 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 will be published in the Federal Register, which proposes to amend 42 CFR, Chapter IV, Part 401 by adding Subpart G – Availability of Medicare Data for Performance Measurement. The NPRM includes a description of 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. Burden Estimates (Hours & Wages)

Because section 1874(e) establishes a new program, there is little quantitative information available to inform our estimates. However, we believe that many or most qualified entities are likely to resemble community quality collaborative programs such as participants in the CMS Better Quality Information for Medicare Beneficiaries pilot (<https://www.cms.gov/BQI/>) and the AHRQ Chartered Value Exchange (CVE) program (<http://www.ahrq.gov/qual/value/lncveover.htm>). Community quality collaboratives are community-based organizations of multiple stakeholders that work together to transform health care at the local level by promoting quality and efficiency of care, and by measuring and publishing quality information. Consequently, we have examined available information related to those programs to inform our assumptions, although there is only limited available data that is directly applicable to this analysis.

We estimate that 35 organizations will submit applications to participate as qualified entities. We anticipate that the majority of applicants will be nonprofit organizations such as existing community collaboratives. In estimating qualified entity impacts, we used hourly labor costs in several labor categories reported by the Bureau of Labor Statistics (BLS) at <http://data.bls.gov/pdq/querytool.jsp?survey=ce>. We used the annual rates for 2009 and added 33 percent for overhead and fringe benefit costs. These rates follow:

Labor Category	2009 hourly wage rate	Overhead/ fringe (33%)	Total hourly cost
Professional & technical services	\$34.08	\$11.25	\$45.33
Legal services	\$35.35	\$11.67	\$47.02

We estimate that the initial preparation of an application will require a total of 500 hours of effort, requiring a combination of staff in the professional and technical services and the legal labor categories, as follows:

<u>Activity</u>	<u>Hours</u>	<u>Hourly cost</u>	<u>Cost per applicant</u>	<u>Number of applicants</u>	<u>Total costs .</u>
Prepare draft application	360	\$45.33	\$16,319		
Legal review	40	\$47.02	\$1,881		
Revisions to draft application	60	\$45.33	\$2,720		
Senior management review and sign-off	40	\$45.33	\$1,813		
Total	500		\$22,733	35	\$795,641

From this, we estimate that the cost per organization for applying initially to be a qualified entity will be \$22,733, and we estimate that 35 organizations will apply. The initial total annual hour burden will be 17,500 hours and the total annual cost will be \$795,641.

Organizations initially approved to be qualified entities will need to re-apply every two 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:

<u>Activity</u>	<u>Hours</u>	<u>Hourly cost</u>	<u>Cost per applicant</u>	<u>Number of applicants</u>	<u>Total costs .</u>
Prepare draft application	86	\$45.33	\$3,898		
Legal review	10	\$47.02	\$470		
Revisions to draft application	14	\$45.33	\$635		
Senior management review and sign-off	10	\$45.33	\$453		
Total	120		\$5,456	25	\$136,400

From this, we estimate that the cost per organization for re-applying to be a qualified entity will be \$5,456, and we estimate that 25 organizations will be initially approved and re-apply. The total hour burden for re-applying will be 3,000 hours and the total cost will be \$136,400.

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 full time equivalent at the GS-13 step 4 level with an annual fully loaded salary of \$158,000, and \$585,000 in contractor support, for a total of \$743,000.

15. Changes to Burden

None, this is a new information collection.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

There are no exceptions to the certification statement.