QUALIFIED ENTITY CERTIFICATION PROGRAM

FOR MEDICARE DATA

2012

OPERATIONS MANUAL

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

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CMS CENTERS for MEDICARE & MEDICAID SERVICES

IMPAQ INTERNATIONAL LLC

NORC at the UNIVERSITY of CHICAGO

NCQA Measuring quality. Improving health care.

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TABLE OF CONTENTS

TABLE OF EXHIBITS

2012 OPERATIONS MANUAL

SECTION 1. OVERVIEW

1.1 ACA SECTION 10332: MEDICARE DATA FOR PERFORMANCE MEASUREMENT

1.1.1 Background

In recent years, a growing number of measurement organizations, health plans, and provider networks, among other **entities**,[1] have conducted a wide range of performance improvement activities and have endeavored to report on the performance of providers. However, these initiatives have mostly been conducted without the benefit of Medicare fee-for-service **claims** data and therefore omit the largest payer of health care services. Effective January 1, 2012, Section 10332 of the Affordable Care Act (ACA) amends Section 1874 of the of the Social Security Act by adding a new subsection (e) requiring standardized extracts of Medicare Parts A and B claims data and Part D drug event data to be made available to ''**qualified entities**'' (QEs) to evaluate the performance of **providers of services (providers)** and **suppliers**. QEs are required to use the information to disseminate CMS-approved public reports regarding the performance of providers and suppliers.

Reports incorporating Medicare fee-for-service claims data into performance initiatives will increase the transparency of provider and supplier performance and be an important driver for improving quality and reducing costs in the Medicare program and the health care system in general. While providing credible and valid information to the public, a program that certifies entities as QEs must also ensure the privacy of Medicare beneficiaries, the security of Medicare data, and fairness to those whose performance is being measured and reported.

To develop a program for entities to become recognized as QEs and to balance the needs of the various stakeholders, CMS solicited public comments through a public Listening Session held on September 20, 2010, and through reactions to the Proposed Rule on "Medicare Program; Availability of Medicare Data for Performance Measurement," published in the *Federal Register* on June 8, 2011. After input from a wide variety of stakeholders, the "Medicare Program; Availability of Medicare Data for Performance Measurement" (hereinafter called the "**Final Rule**") was published in the *Federal Register* on December 7, 2011 (42 CFR, Part 401, Subpart G).

The Final Rule establishes the criteria that entities must satisfy to obtain QE certification and sets forth CMS' expectations for maintaining certification. In particular, the rule provides requirements for entities in the following areas:

- Organizational structure and governance criteria, including necessary experience and expertise in the measures entities intend to use;
- Expertise in combining Medicare claims data with **claims data from other sources**; and
- Expertise in establishing rigorous data privacy and security programs

[1] Selected terms in bold font are defined in the Glossary (Appendix E).

The **Qualified Entity Certification Program for Medicare Data (QECP)** was developed to implement the Final Rule. This **Operations Manual** is intended to guide entities through the QECP. It includes all CMS requirements that **prospective applicants** must meet to become certified as QEs and to maintain their QE status, as well as step-by-step instructions on the application process. It is intended to be used as a resource by prospective applicants, **applicants**, QEs, and other stakeholders interested in the functioning of the program.

1.1.2 Principles of the QECP

The QECP is designed to evaluate existing performance reporting entities for their ability to function as QEs and, contingent on the entities meeting or exceeding certain standards, to provide them with Medicare data to enhance their current performance measurement efforts. The following principles guided the development of the QECP:

- *Public reporting of provider and supplier performance*: Performance reports produced by qualified entities will be an important driver of improving quality and reducing costs in Medicare as well as in the health care system in general. The QECP will increase the transparency of provider and supplier performance while ensuring beneficiary privacy.
- *Transparency*: To ensure the credibility of the measures—both to those who are evaluated and to those who make use of the results—the performance reporting process must be sufficiently transparent. QEs must provide detailed, clear descriptions of the methodologies they will use to evaluate the performance of providers and suppliers. Providers and suppliers must have confidence that the results are accurate. Reports generated by the QEs may not be released to the public until the providers and suppliers have had the opportunity to review them and request corrections. Performance reports, containing clear descriptions of the methodologies used, must be made available to the public.
- *Standardization and Sound Methodology of Measures*: Standardized and well-specified measures that follow tested methodologies allow results to be compared credibly across providers or organizations. Qualified entities are required to use **standard measures** or approved **alternative measures** for evaluating the performance of providers and suppliers.
- *Privacy and Protection*: The success of the QECP hinges on the ability of CMS to provide Medicare data to QEs for performance reporting while protecting the identities of Medicare beneficiaries throughout every phase of the process. It is of the utmost importance to CMS that beneficiary identifiable health information remains private and secure. Later sections of this manual provide a detailed explanation of the rigorous administrative, technical, and physical data security and privacy program policies and requirements.
- *Evaluation, Monitoring, and Oversight*: CMS has previously never made Medicare Parts A and B claims data and Part D drug event data available on this scale. Ongoing evaluation, monitoring, and oversight by CMS are necessary to ensure that QEs have the infrastructure and policies necessary to meet the program's requirements and that they follow best practices once they receive Medicare data.

1.1.3 QECP Operations

CMS contracted with IMPAQ International, LLC and its partners (the QECP team) to assist in developing, implementing, and managing the QECP. The team includes:

- IMPAQ International, LLC (IMPAQ), a research organization with demonstrated expertise in performance measurement, program evaluation, handling and processing of Medicare claims, and management of large multi-task CMS projects;
- National Committee for Quality Assurance (NCQA), a recognized leader in health care performance measurement development, implementation, and evaluation, with 20 years of experience helping health care entities define methods for ongoing improvement;
- NORC at the University of Chicago (NORC), a research organization with significant expertise in privacy and data confidentiality and systems security with particular experience in Medicare and Medicaid data; and
- Buccaneer Computer Systems & Services (Buccaneer), a company highly experienced in data infrastructure, data management, and delivery of CMS data, including the national Medicare and Medicaid research database (Chronic Condition Data Warehouse).

Drawing on its considerable expertise with Medicare claims data, performance and reporting standards, and collaboration with a wide variety of stakeholders, the QECP team worked closely with CMS to develop **minimum requirements** for the QECP and to establish processes for receiving and reviewing **applications** for QE certification. Under the guidance of CMS, the QECP team will update and refine QECP requirements; provide technical assistance to applicants and QEs; establish post-QE certification evaluation, monitoring, and oversight; and ensure the overall successful implementation of the QECP.

1.2 OPERATIONS MANUAL

The Operations Manual is the key information and procedural reference document for all entities and individuals interested in the purpose and function of the QECP. The purpose of the Operations Manual is to translate the policy outlined in the Final Rule into concise requirements and procedures so that the main objective of ACA Section 10332 is met, namely, that QEs receive Medicare data to evaluate the performance of providers and suppliers while ensuring privacy for beneficiaries and fairness for providers and suppliers. To this end, the Operations Manual includes an overview of the fundamental aspects of the QECP; the minimum qualifications that an interested entity must meet to become a certified QE; and the policies and procedures that must be followed for an entity to maintain certification as a QE.

1.2.1 Operations Manual Annual Releases

The Operations Manual will be released annually. This first annual Operations Manual (2012 Operations Manual) includes all necessary information and procedures for first-time QE

applicants for certification. Its publication satisfies the Federal mandate that Section 10332 of the ACA become effective as of January 1, 2012.

The 2013 Operations Manual, which will be available in February 2013, will include updates to the program, and specify in more detail the criteria for monitoring and oversight, which will commence after the evaluation phase, at the earliest, in 2013. Such criteria may include requirements for QE annual report submissions, information systems assessment, supporting documentation submissions, and quality assurance plans.

1.2.2 Operations Manual Update Releases

After each annual release of the Operations Manual, an **Operations Manual Update** will be released as a stand-alone document, typically within several months of the annual Operations Manual release. The update will provide any needed clarifications or additional program requirements not covered in the Operations Manual. Prospective applicants and QEs will be required to incorporate and adhere to the requirements in the annual update once it is released.

The 2012 Operations Manual Update will be released during the second quarter of 2012. Because this is the first year of the QECP, the update will provide more detail about evaluation requirements subsequent to QE certification and prior to the QE releasing public performance reports. Thus, this update will present the requirements beyond the minimum requirements assessed in the application that QEs must meet prior to releasing their first performance reports under the QECP.

1.2.3 Where to Find Specific Information in the 2012 Operations Manual

See the Overview (Section 1) for…	▪ An overview of QECP participation requirements ▪ An overview of the evaluation, monitoring, and oversight features of the QECP ▪ A description of Medicare Parts A and B claims data and Part D drug event data
See the Policies and Procedures (Section 2) for…	▪ Information on organizations eligible for QE certification ▪ Policies related to the following eight program standards: Applicant Profile, Data Sources, Data Security and Privacy, Methodology for Measurement and Attribution, Measure Selection , Verification Process, Reporting of Performance Information, and Requests for Corrections or Appeals ▪ How to apply to become a QE ▪ Technical assistance information for the QECP application process

- Step-by-step details of the application review process, including timeline
- Application review outcomes and notifications
- How to request Medicare data after QE certification
- An explanation of how Medicare data will be encrypted and transferred to QEs upon certification
- Technical assistance information for Medicare data and data transfer
- How to report governance and public reporting changes to QECP and which changes must be reported
- QE evaluation, monitoring, and oversight components
- Maintaining/losing QE certification status
- Consequences for non-compliance with QECP regulations

See the Minimum Qualifications/Standards (Section 3) for…

- The standards that entities must meet to become a QE
- The elements that constitute each standard
- The assessments to be performed by application reviewers to determine compliance with each element
- Recommended evidence for demonstrating an entity's compliance with each element

See the Appendices for…

- A diagram of the QECP process
- The QE application form, including a summary table of the QECP minimum requirements
- Qualified, conditional status application process
- Instructions on how to navigate the QECP Portal (User's Guide)
- Glossary of terms used in the Operations Manual

Other Important Information

- General information about the Medicare Data for Performance Measurement initiative, the QE application, and frequently asked questions (FAQs) related to the application process: http://www.QEMedicareData.org
- Final Rule: http://www.gpo.gov/fdsys/pkg/FR-2011-12-07/pdf/2011-31232.pdf
- Patient Protection and Affordable Care Act (see Section 10332): http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590pp/html/BILLS-111hr3590pp.htm

- General information about the Medicare Data for Performance Measurement initiative, Data Use Agreement instructions, payment processing, Medicare data training opportunities, and data corrections procedures: http://www.resdac.org/QEMedicareData.asp
- CMS general information page for the Medicare Data for Performance Measurement initiative, which also directs individuals to the appropriate resources for applying to become a QE and requesting Medicare data: http://www.cms.gov/QEMedicareData

1.3 PROGRAM PARTICIPATION REQUIREMENTS

1.3.1 Requirements

To participate in the QECP, entities must:

- Apply for and receive QE certification: https://www.QEMedicareData.org/SitePages/register.aspx;
- Submit a data request packet, including a Data Use Agreement (DUA), and obtain CMS approval: http://www.resdac.org/docs/CMS-R-0235-QE-508-user.pdf;
- Submit payment to CMS for the fees to cover the cost of the Medicare data: http://www.resdac.org/QEMedicareData.asp; and
- Comply with the program's evaluation, monitoring, and oversight requirements.

Entities that apply for and meet the set of minimum requirements, obtain and execute a CMS **Data Use Agreement (DUA)**, pay the associated fee for data production and delivery, and comply with evaluation, monitoring, and oversight activities are certified for 3 years. While a single entity may seek to fulfill all of the program requirements, a qualified entity may also be a group of two or more entities that use contractual relationships to address any requirements that a single **lead entity** may lack. All entities that contract with the lead entity to meet the requirements of the program and that anticipate use of and access to Medicare data or **beneficiary identifiable data** are required to sign the DUA. After the entity has been certified, the DUA has been approved, payment has been received, and data have been transmitted, the QE may evaluate and publicly report on the performance of providers and suppliers with respect to quality, efficiency, effectiveness, and resource use measures. Section 2 of this manual provides additional details about the policies and procedures regarding certification, data requests, and data transmission.

1.3.2 Estimated Timeframes

The application **review** process, including CMS' final outcome decision, is estimated to take up to 55 business days if all requirements are met during the initial review. For applicants that

require and are granted more time to meet certain **standards**, the application review process may take up to 145 business days. After certification, the processes for DUA approval, payment, and initial data transmission are estimated to take 25 business days.

1.4 EVALUATION, MONITORING, AND OVERSIGHT

Evaluation, monitoring, and oversight begin after an entity has been successfully certified as a QE and has received **standardized data extracts**. The evaluation phase occurs after certification and prior to public reporting. This includes an additional review of specific requirements set forth in the application to ensure the QE's capability to continue to meet these requirements after it integrates Medicare data into its measurement and reporting processes. Approximately one year following an entity's certification (thus starting in 2013 for QEs certified in 2012), monitoring and oversight of the QE will commence. Through monitoring and oversight, CMS will observe the QE's processes to promote ongoing compliance. All QEs will be subject to evaluation, monitoring, and oversight.

A QECP process flow diagram explaining the major program processes from the point of prospective applicant registration to QE monitoring and oversight may be found in Appendix A.

1.5 MEDICARE DATA

Medicare Parts A and B claims data and Part D drug event data will be provided to the QE for its CMS-approved geographic area. These data files will be extracted and delivered by the national Medicare and Medicaid research database, referred to as the CMS **Chronic Condition Data Warehouse (CCW)**. State-specific data files (based on a beneficiary's state of residence) will be linked over time by a unique beneficiary identifier (BENE_ID). Although the CCW data files do not contain beneficiary names, Medicare Health Insurance Claim (HIC) numbers, or Social Security Numbers (SSN), they are considered identifiable because they contain beneficiary demographics, such as date of birth, zip code, county, gender, and other information that could potentially be used to reidentify an individual. For QEs requiring linkage to other data sources containing name, HIC number, or SSN, the CCW will provide a crosswalk from the BENE_ID to such variables.

The **Medicare Part A claims data** consist of fee-for-service claims from institutional health care providers, including inpatient, skilled nursing facility, outpatient, hospice, and home health (see Glossary, Appendix E, for a description of each type).

The **Medicare Part B claims data** consist of fee-for-service claims from non-institutional health care providers, including carrier and durable medical equipment regional carrier (see Glossary, Appendix E, for a description of each type).

The **Medicare Part D prescription drug event (PDE) data** consist of summary records submitted by prescription drug plan sponsors. A PDE is recorded each time a beneficiary fills a prescription.

In addition to the claims data provided to QEs, demographic and enrollment information is available from the **Beneficiary Summary File**. This file contains state and county of residence codes, zip code, date of birth, date of death, sex, race, age, monthly entitlement indicators (A/B/C/D), reasons for entitlement, state buy-in indicators, and monthly managed care indicators (yes/no). From 2006 forward, it also includes variables specific to enrollment in the Medicare Part D prescription drug program. These variables include a derived race/ethnicity code, an indicator for Other Credible Drug Coverage, and monthly indicators for Medicare Advantage Prescription Drug (MA-PD) or stand-alone Prescription Drug Plan (PDP) enrollment, Low Income Subsidy (LIS) enrollment, Retiree Drug Subsidy, and state-reported dual eligibility status.

The standard file record layouts for all CCW files may be found at http://www.ccwdata.org/ (see Data Dictionaries tab). The data files provided to QEs will follow this record layout format but will be segmented by beneficiary's state of residence (from the Beneficiary Summary File). State-specific data files will be provided to QEs only for those states listed in the CMS-approved DUA. In addition, if QEs intend to calculate national benchmarks for their performance measures, they have the option to request 5% national sample files for such purposes.

Section 2.13 of this manual provides additional details regarding data request and data transmission procedures.

2012 OPERATIONS MANUAL

SECTION 2. POLICIES AND PROCEDURES

2.0 INTRODUCTION TO QECP STANDARDS

Any entity capable of meeting the requirements set forth in the QE application may be certified as a qualified entity. Qualified entities are not required to be a single legal entity. Multiple entities may contract with one another to achieve the ability to meet the eligibility standards; however, there must be one lead entity responsible for the application process and ongoing certification. The QECP design allows for broad inclusion of all types of entities that currently evaluate providers and share performance reports with the public. The application requirements of the program offer a guide to the first steps in verifying whether an entity and its contracted entities may function as a QE.

Any entity interested in becoming a QE must supply **evidence** of meeting the following eight standards:

- Applicant Profile
- Data Sources
- Data Security and Privacy
- Methodology for Measurement and Attribution
- Measure Selection
- Verification Process
- Reporting of Performance Information
- Requests for Corrections or Appeals

While any public or private entity may apply to be certified as a QE, CMS requires entities to have established performance reporting programs. Beyond this general description, any entity or contractually obligated group of entities capable of meeting the minimum requirements may become a QE. These requirements are summarized in this section, presented in full in Section 3, and listed in the paper-based QE Application Form (Appendix B).

2.1 STANDARD 1 – APPLICANT PROFILE

Applicants must demonstrate an understanding of how they plan to use the Medicare data, as well as an ability to cover the costs associated with functioning as a QE. Applicants must present information about the type of entity, whether they are applying as a single entity or if contractual arrangements exist for the purposes of the QECP, and which areas in the United States they are planning to assess provider or supplier performance.

2.2 STANDARD 2 – DATA SOURCES

This standard assesses the sources and types of claims data to which the applicant has access for the purposes of QECP performance measurement. Applicants must have at least one additional source of claims data from relevant geographic (state) areas at the time of

application (the exception is those entities applying for qualified-conditional certification: see Appendix C). While the QECP does not establish an absolute threshold for a minimum amount of additional claims data, applicants must demonstrate that the amount of claims data, when combined with the requested Medicare claims data, is adequate to address concerns about small sample size and reliability. Elements 4C and 4D assess this requirement.

Clinical data may be used when the approved standard or alternative measures specify the use of clinical data in combination with Medicare claims and other claims data to calculate performance.

2.3 STANDARD 3 – DATA SECURITY AND PRIVACY

Entities must demonstrate that they have rigorous security and privacy practices in place to protect the data released to them and have programs in place to enforce and monitor data security practices. Stringent security and privacy standards must be enforced throughout all phases of the program, including data receipt or transmission, performance measure calculation, the provider review and corrections process, and performance reporting (including all public reporting as well as any other types of more limited reporting). Although applicants are required to submit any disclosures of beneficiary identifiable information from the past 10 years (or lifetime of the entity if less than 10 years), this disclosure will not automatically disqualify an entity from participating in the program.

2.4 STANDARD 4 – METHODOLOGY FOR MEASUREMENT AND ATTRIBUTION

This standard assesses the applicant's ability to accurately calculate quality and efficiency, effectiveness, or resource use measures from claims data for measures it intends to calculate with Medicare data. This includes, for example, assessing the applicant's ability to adhere to measure specifications, attribute performance results, and define and identify appropriate peer groups and benchmarks. The standard further assesses whether, as specified and based on the applicant's available claims data (including the requested Medicare claims data), the proposed measures meet required scientific properties, for example, sufficient sample size, reliability, and validity. Applicants are only required to submit evidence for Element 4D if they select efficiency, effectiveness, or resource use measures to evaluate providers or suppliers.

2.5 STANDARD 5 – MEASURE SELECTION

This standard assesses the measures the applicant selects to evaluate providers or suppliers. This includes an assessment of the scientific properties of the selected measures, for example, validity and reliability.

2.5.1 Standard Measures

Standard measures are claims-based measures that may be calculated in full or in part from standardized extracts of Medicare Parts A and B claims data and Part D PDE data and must fall into one of the following categories:

- *Measures currently used in CMS programs that include quality measurement:* These measures have been adopted through notice and comment rulemaking that includes a public comment period. Examples include measures used in the CMS hospital Inpatient Quality Reporting (IQR) program.
- *National Quality Forum (NQF)-endorsed measures*: NQF is contracted by the Federal government under Section 1890(a) of the Social Security Act to establish a portfolio of quality and efficiency measures for use in public reporting and health care quality improvement. NQF endorses measures through consensus by seeking the input of stakeholders across the health care industry as well through public comment. NQF-endorsed measures may be found at http://www.qualityforum.org/measures_list.aspx.
- *Measures endorsed by a CMS-approved consensus-based entity:* CMS will approve organizations as consensus-based entities based on review of documentation of stakeholder consultation and the measure approval process. The process for approving consensus-based entities is currently under development. Interested entities should check the website http://www.QEMedicareData.org for additional information as the process is developed.

A reference list of standard measures will be available on http://www.QEMedicareData.org. However, entities are responsible for independently checking known standard measure sources for the most complete and up-to-date information.

2.5.2 Alternative Measures

Qualified entities generally must use standard measures for evaluating the performance of providers and suppliers unless the use of alternative measures would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures. If a standard measure exists for the clinical or topic area addressed by the alternative measure, the entity must provide detailed scientific justification for using the alternative measure instead of the standard measure. The alternative measure will be accepted either through the notice and comment rulemaking process or through a stakeholder consultation approval process in which entities proposing alternative measures submit supporting documentation that outlines the consultation and agreement with appropriate stakeholders in the community. Applicants are not required to select alternative measures; therefore, applicants are only required to submit evidence for Element 5B if they select an alternative measure to evaluate providers or suppliers.

The process for submitting measures for notice and comment rulemaking is currently under development. Interested entities should check the website http://www.QEMedicareData.org for additional information as the process is developed.

To obtain approval of an alternative measure by demonstrating stakeholder consultation approval, the following information must be provided for each alternative measure:

- Description of the process by which the entity notified stakeholders in the geographic region it serves of its intent to seek approval of an alternative measure. Stakeholders must include a valid cross representation of providers, suppliers, payers, employers, and consumers.
- A list of stakeholders from whom feedback was solicited, including the stakeholders' names and roles in the community.
- A description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments supporting and opposing the measure.
- An explanation, backed by scientific evidence, which demonstrates that the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use than existing standard measures.

If a newly endorsed standard measure is equivalent to an approved alternative measure, within 6 months of the standard measure's endorsement QEs must either transition to the standard measure or submit scientific justification and receive approval to continue use of the alternative measure. Additional information regarding this transition will be available in the 2012 Operations Manual Update, to be released during the second quarter of 2012.

QEs may request approval to modify approved standard and alternative measures or add new measures to their QECP reporting activities. However, QEs may not report modified or new measures until they receive approval from CMS (see Section 2.14). The requirements QEs must meet for final approval of modified or new measures will be described in the 2012 Operations Manual Update (to be released during the second quarter of 2012).

2.6 STANDARD 6 – VERIFICATION PROCESS

This standard assesses the applicant's ability to verify and correct measurement and reporting errors and processes. The verification or quality assurance process must be performed at least annually.

2.7 STANDARD 7 – REPORTING OF PERFORMANCE INFORMATION

This standard assesses the applicant's dissemination plan and report prototypes, including the narrative language the applicant plans to use in the reports to describe the data and results. The dissemination plan must describe the entity's proposed information dissemination

strategy. If QEs intend to release different reports to the public and to providers and suppliers, both report prototypes, including the narrative language, must be submitted as part of the application.

Because QEs may alter their final dissemination approach and report prototypes after the application is complete, it may be necessary for QECP reviewers to assess and approve the updated dissemination plan and reports. QEs may not release performance reports to providers, suppliers or the public until their final dissemination approach and report formats have been approved. The requirements QEs must meet for final approval of performance reports will be described in the 2012 Operations Manual Update (to be released during the second quarter of 2012).

If a QE wishes to change its dissemination plan or report prototypes after approval, CMS requires at least 30 days to review and approve the updated plans and prototypes (see Section 2.14).

2.8 STANDARD 8 – REQUESTS FOR CORRECTIONS OR APPEALS

QEs are required to confidentially share performance results with the providers and suppliers that are being evaluated and to allow for corrections prior to public reporting. QEs must provide the measure name/description, methodology, and results to providers and suppliers at least 60 calendar days prior to making the measure results public. QEs must inform providers and suppliers of the date the reports will be made public at least 60 calendar days in advance. The qualified entity must publicly release reports on the specified date regardless of the status of any requests for error correction.

As previously stated, because QEs may alter their corrections process and report prototypes after the application is complete, it may be necessary for QECP reviewers to assess and approve the updated process and reports. QEs may not release reports for the corrections process to providers and suppliers until their final dissemination approach and report formats have been approved. The requirements QEs must meet for final approval of their corrections process will be described in detail in the 2012 Operations Manual Update (to be released during the second quarter of 2012).

2.9 EVALUATION, MONITORING, AND OVERSIGHT OF QES

The ability of a QE to comply with program requirements for robust measurement methodologies and dissemination of results while maintaining a high level of security is critical to the success of the program. The assessment of QE performance will include criteria to validate the QE's performance against all program requirements. The minimum qualifications set forth in the application are the foundation for obtaining certification as a QE. Although

establishing minimum qualifications is critical, processes must be defined to establish compliance with these qualifications once the Medicare data are received. The QECP will first evaluate a QE's ability to meet the program requirements prior to the release of the QE's first performance reports; thereafter, the QE will be required to comply with all monitoring and oversight requirements.

Program evaluation and monitoring will be scheduled once the QE is certified and receives data. Oversight will be ongoing.

2.9.1 Evaluation

Prior to the reporting of any performance results, QEs will be required to demonstrate their ability to use Medicare data consistent with the documented plans they presented at the time of application. This includes additional assessment of specific standards to ensure the QE's ability to accurately and securely integrate Medicare data. The evaluation includes additional assessment of the following requirements:

- Data security and privacy
- Data capture, transfer, and integration with other claims data
- Measure calculation, reliability, and validity
- Request for corrections process
- Public reporting

Details about how to demonstrate compliance with these evaluation requirements will be released in the 2012 Operations Manual Update. QEs will need to complete evaluation before they produce and publicly distribute performance reports containing Medicare data. Once a QE has successfully completed at least one cycle of public reporting, it will move into the QECP monitoring phase.

2.9.2 Monitoring

CMS will monitor and assess the performance of qualified entities through several mechanisms, including the submission of documentation by the QEs and onsite visits. Program monitoring is initiated once a QE has successfully released its first public report that incorporates Medicare data.

Monitoring assessments will be conducted remotely and during planned onsite visits. Site visits will provide CMS the opportunity to directly monitor the performance of the QEs. The QE applicant lead and contracted entities or partners may be subject to an onsite monitoring visit.

Further detail about the monitoring process, including the onsite visits, will be published in the 2013 Operations Manual (to be released in February 2013).

2.9.3 Oversight

QEs will be subject to ongoing program oversight. As part of this oversight, QEs will be required to submit an annual report covering program adherence (e.g., number of claims, market share, number of measures) and engagement of providers and suppliers (e.g., number of requests for corrections, time to respond to requests for correction). Furthermore, oversight may result in identifying problems, introducing solutions, monitoring the effectiveness of the solutions, and requesting a QE to develop procedures or implement a corrective action plan to bring it into full compliance with program requirements.

A fundamental component of meeting the QECP monitoring and oversight requirements is the QE's development and implementation of a quality assurance plan that adheres to the QECP's quality assurance requirements. The ability of a QE to comply with program requirements for robust measurement methodologies and dissemination of data while maintaining a high level of security is critical to the success of the program.

Further details about the oversight process and quality assurance requirements will be published in the 2013 Operations Manual (to be released in February 2013).

2.10 APPLICATION SUBMISSION

2.10.1 QECP Portal

The **QECP Portal** is designed to facilitate the application and certification processes. This online tool supports the submission, review, and approval of applications from entities. Entities interested in applying for certification may access the portal to review application requirements and complete and submit the application electronically. The portal also facilitates ongoing technical support throughout the application process (see Section 2.10.3). After an entity submits an application through the portal, the entity may access the portal to monitor the progress of the review process and certification status. If an entity is certified, a letter from CMS will be sent signifying its certification as a QE.

Entities perform the following key steps to submit an application:

- Complete registration to obtain an administrative profile for the QECP Portal;
- Access critical documents about the QECP Portal and the application process;
- Read the Operations Manual and QECP Portal User's Guide;
- Access the application page and complete the application;
- Review and finalize the application, including all required evidence as attachments; and
- Submit the application.

The QECP Portal User's Guide (Appendix D) provides detailed instructions on how to navigate the website, access materials, complete the registration and application materials, submit the application materials, and request technical assistance.

Entities interested in obtaining general information or registering for access to the QE application may visit the publicly accessible portion of the QECP Portal at http://www.QEMedicareData.org.

2.10.2 Applying for the QECP

2.10.2.1 Requesting Accounts for the QECP Portal

A representative from each entity that intends to apply for QE certification must access the QECP Portal and complete the **registration form**. Registration allows access to restricted QECP portal modules, which are not publicly accessible. Once a registration form is submitted by an entity, the entity's representative receives a link to the Operations Manual and is assigned a unique user ID and password and a secure application site for that entity only. For the duration of the application process this user will be identified as the entity's **administrative user.** To obtain additional accounts for the same entity, **additional users** must also register by completing the registration form. To receive a unique user ID and password, each additional user must receive the administrative user's approval. Technical support is available for entities to submit questions about registration or the general certification process at support@QEMedicareData.org.

2.10.2.2 Accessing Critical Documents via the QECP Portal

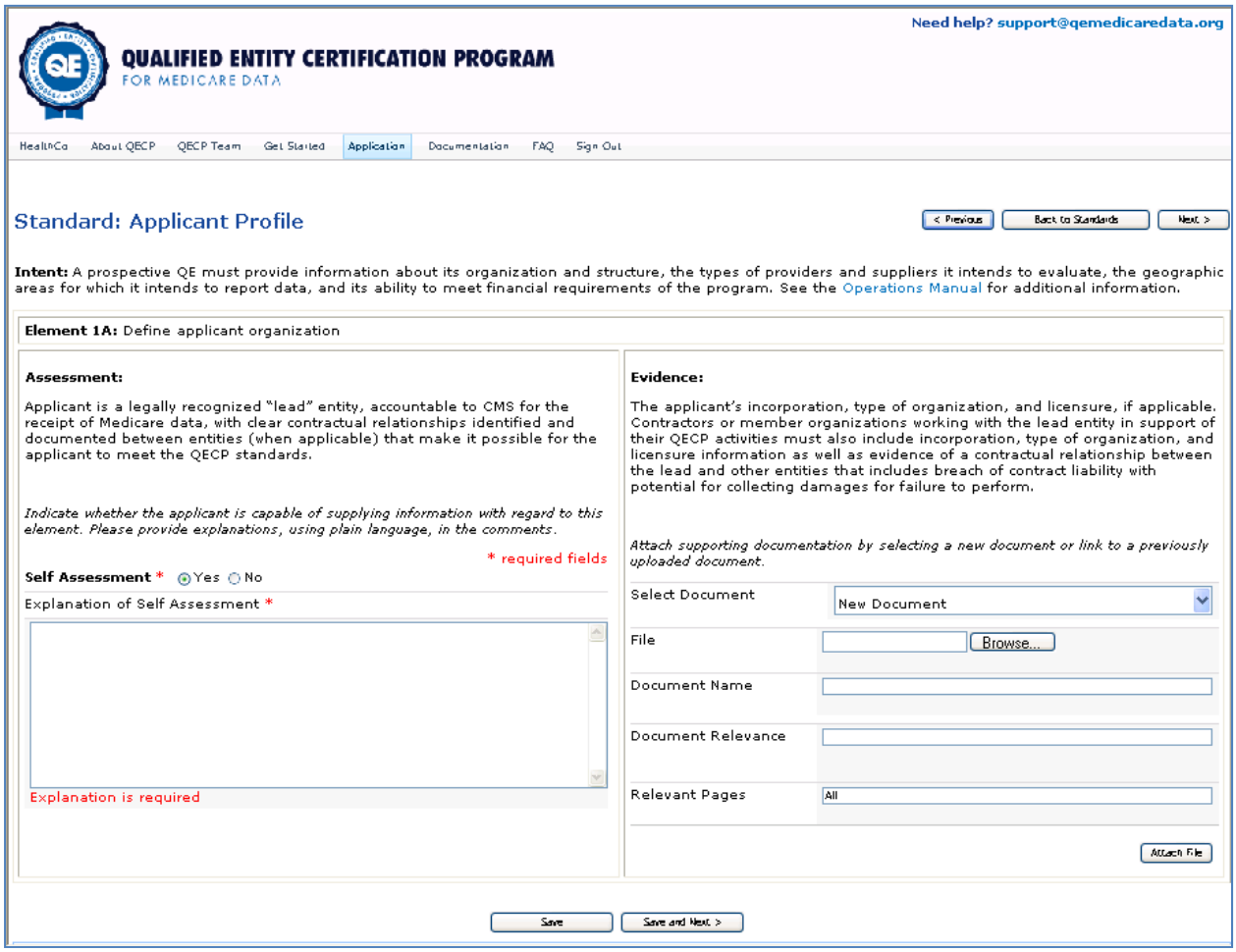
Once entities have completed the registration process and an administrative user ID and password have been issued, the administrative user and any approved additional users may access the application through a secure channel of the portal website. To begin the application, users are encouraged to access the *Documentation Library* and review all available documents, and specifically this Operations Manual and the paper-based QE application form (see Appendix B) before beginning the application. Section 3 of this manual provides details on the minimum requirements for becoming a QE and the necessary supporting documentation or evidence that must be submitted.

2.10.2.3 Completing the Application Form

After reviewing the minimum requirements, entities may access the QE application form on the *Application* page. Though paper-based QE application forms exist, entities are requested to complete the QE application form online via the QECP Portal. Registered users may save the application at any time and return to it later. Once a user saves the information entered in the online application, it becomes available to other users associated with that entity. Therefore, multiple users from the same entity may work on the application at the same time; however, only the saved information is visible.

Exhibit 1 provides a screenshot of the QE application form for Standard 1 (Applicant Profile), Element 1A (Define Applicant Organization). All supporting or evidentiary documents may be uploaded to the QECP Portal and submitted as attachments to the online application. A complete paper-based version of the QE application form may be found in Appendix B. In completing the application form, prospective applicants are required to **self-assess** their ability to meet the minimum requirements of the QECP by answering "yes," "no," or "n/a" to each assessment and elaborating in the comment box if they are unable to meet a particular assessment.

Exhibit 1: QE Online Application Form Screenshot



2.10.3 QECP Portal Technical Support

The following technical support resources are available to all entities before, during, and after the submission of QE applications:

- Frequently Asked Questions (FAQs):
  https://www.QEMedicareData.org/SitePages/faq.aspx
  Entities are encouraged to review the FAQs prior to seeking other technical support avenues. FAQs will be updated on a regular basis.

- Email: support@QEMedicareData.org
  Email responses will be sent within 2 business days.

- Toll-free Helpline: (866) 277-9966
  Telephone calls will be returned within 2 business days.

2.11 APPLICATION REVIEW PROCESS

The application review to certify entities as qualified entities includes a web-based step-wise process. The allotted review period of 55 business days for a single application starts after an application is submitted and validated. Clarification or updates to existing evidence may be requested by reviewers once the application review process starts.

In the web-based review process, applications are subject to multiple reviewer assessments of compliance with standards and **elements**. The application review begins immediately upon submission of a complete and validated application. Using the QECP Portal designed for this program, reviewers will assess the entity's compliance with the standards (met/not met), based on the supporting documentation and evidence provided. In addition, the reviewers will identify potential opportunities for improvement in areas that are deficient or require additional clarification. The review results are included in a report of findings and recommendations; the final decision report from CMS will include a final outcome for the entity as either "Qualified" or "Not Qualified."

QECP technical support is available to assist prospective applicants in their preparation, as indicated in Section 2.10.3. All prospective applicants are encouraged to utilize these resources and consult the Operations Manual as they prepare to submit evidence of their capabilities to function as a QE. The following subsections describe the steps involved in the application review process.

2.11.1 Prospective Applicant Completes Registration and Gains Access to Application Form

The prospective applicant submits information about the entity (name/location of entity and contact information) via the publicly accessible portion of the QECP Portal to obtain an administrative user ID and password and gain access to the application form. This step is the first indication of an entity's interest in the QECP.

2.11.2 Confirm Intent and Planned Submission

Using the provided contact information, the designated **program coordinator** contacts the entity to determine when the entity anticipates submitting an application.

2.11.3 Application Is Submitted

The entity completes and submits its application as final according to the instructions in the QECP Portal User's Guide (Appendix D).

2.11.4 Application Is Validated

The program coordinator assesses the application, ensuring that all elements have evidence attached and that complete contact information is provided. If the application is considered complete, the program coordinator flags it as a "valid application" and at this point the entity becomes an "**applicant**." The applicant is notified that the application has been accepted and that the **validation** is complete. The program coordinator notifies the applicant's **review coordinator** and the application review is initiated.

If an application is considered incomplete, the applicant will be notified and the application will not be reviewed further. For the application to proceed in the process, the applicant must revise and resubmit the application until it is deemed valid by the program coordinator. Technical assistance is available throughout the application process.

2.11.5 Application Is Reviewed

Once the application review is initiated, the **review team** (review coordinator, **administrative reviewer** and **executive reviewer**) assess the applicant's submitted evidence and self-assessment for each element against the program's minimum requirements.

2.11.6 Review Team Holds Conference Call with Applicant

Via a conference call, the review team and the applicant have an opportunity to discuss feedback and to identify and correct any outstanding issues. Following the conference call, applicants have 5 business days to clarify any submissions or respond to the review

coordinator's requests. This is the applicant's opportunity to provide a rebuttal to reviewer findings; applicant rebuttals are included in the QECP team's final recommendation report to CMS.

The applicant may be granted additional time during the application review to meet the requirements for Standard 3 in order to be fully compliant with the data security and privacy requirements. This will be identified and discussed during (or before) the conference call. Specifically,

- Applicants compliant with all other elements but not meeting an element under the Data Security standard may be required, as determined by the executive reviewer, to submit a **plan of action and milestones (POA&M)** addressing identified deficiencies. The review coordinator notifies the applicant of this request. The applicant has 5 business days to complete and submit a POA&M (within 30 business days of application validation). After submission of the final POA&M, an applicant has no more than 90 business days to complete agreed upon and identified milestones. The executive reviewer then has 10 business days to evaluate the completion of the applicant's POA&M. If the executive reviewer determines that the deficiencies have not been remediated within this timeframe, the applicant may withdraw the application or may proceed, with the understanding that a final decision by CMS determining non-compliance with any one element will result in an outcome of Not Qualified.

The applicant may be allowed to revise evidence submitted under the measure selection standard (standard 5) in order to be fully compliant. This will be identified and discussed during (or before) the conference call. Specifically,

- If the evidence submitted for a standard or alternative measure (Elements 5A and 5B, respectively) is determined to be inadequate during the application review, the applicant has the option of withdrawing the measure and proceeding with the application process. If the applicant opts not to withdraw the measure in question, the application may proceed, with the understanding that a final decision by CMS determining non-compliance with any one standard will result in an outcome of Not Qualified.

2.11.7 CMS Decision Is Rendered

Based on the information provided in the final recommendation report, CMS renders a decision to recognize the applicant as Qualified (a qualified entity) or Not Qualified.

2.11.8 Applicant Is Notified of Outcome

Each applicant will receive a CMS QECP decision report and, if certified as a QE, a list of steps it must take to receive Medicare data.

Post-QE Certification Steps:

- *QE contacts Research Data Assistance Center (ResDAC)*
  Within 10 business days of notification of the outcome, the QE contacts ResDAC to obtain a data request packet and submit all completed forms to CMS. See Section 2.13 of this manual for additional details, including ResDAC contact information.

- *QE pays Medicare data dissemination fees to CMS*
  CMS estimates and collects the program fees from the QE.

- *QE receives Medicare data*
  CMS releases the approved Medicare data to the QE and notifies the reviewers of the date of data delivery. The QE will receive access to Medicare data within approximately 80 business days of application initiation.

2.12 APPLICATION REVIEW OUTCOMES

There are only two final outcomes for the QECP application review: (1) Qualified and (2) Not Qualified. An applicant that meets all program requirements except that it does not, at the time of application, have any or sufficient other claims data (Element 2A) may opt to undergo a QECP Conditional Status application review. However, this is not a final outcome; entities with conditional status will not be eligible to receive Medicare data. See Appendix C for additional details regarding QECP Conditional Status.

2.12.1 Qualified

An applicant will receive a status as Qualified (*qualified entity*) if it demonstrates complete compliance with the requirements in the application. This status is valid for 3 years from the date of notification of CMS approval unless a QE's status is otherwise terminated. CMS will publicly announce on the CMS website (http://www.cms.gov/QEMedicareData) the names of those applicants that have been certified as QEs.

QE status is valid for 3 years from the date of notification of CMS approval. The QE must submit data requests and fees to receive quarterly updates of Medicare data until the last 6 months of its qualification period. At that time, the entity must **re-apply** to QECP and undergo another review to continue receiving data.

2.12.2 Not Qualified

An applicant will receive a status as Not Qualified if it has not met the requirements for certification. Failure on any single element will result in an outcome of Not Qualified. The names of applicants who receive an outcome of Not Qualified will not be announced publicly.

2.12.2.1 Disclaimer

To arrive at each applicant's final certification outcome, the QECP review team (as CMS' agent) evaluates the final application against the minimum requirements for a qualified entity. The review team's assessment of the organization is based on its professional, evaluative judgment. Meeting the minimum requirements does not guarantee certification. Determination of certification status is made by CMS.

2.12.2.2 Repeat Applications

An applicant that received an outcome of Not Qualified may apply twice within a 12-month cycle. An entity may submit a second application no sooner than 90 business days after the date of its first failure (within the 12-month cycle). If the entity fails the second application, it will be barred from reapplying for 12 months from the date of its second failure.

2.13 MEDICARE DATA: APPLYING FOR ACCESS AND DATA DELIVERY

2.13.1 Applying for Access to Medicare Data

Upon notification of QE certification, the QE must submit a data request package for approval. The Research Data Assistance Center (ResDAC) will be available to assist the QE with the submission of this package (http://www.resdac.org/QEMedicareData.asp, 1-888-9RESDAC, or resdac@umn.edu), including a cost estimate for the data file(s) requested. The ResDAC website provides descriptions of the available CMS data, data request procedures, workshops on how to use Medicare data, and other helpful resources. Within approximately 10 business days of submission of the data request packet, a CMS privacy analyst will notify the QE by email of CMS' approval of the data request.

Upon approval of the data request and assignment of the Data Use Agreement (DUA) number, the QE will be instructed by CMS on how to submit payment to cover the cost of the data files. The cost will be based on the number of files, size of the files, and the number of calendar years of data requested. Receipt of payment will automatically notify CCW staff of approval to proceed with the transfer of Medicare data files to the QE.

2.13.2 Medicare Data Delivery to QEs

Upon CMS approval of the DUA and receipt of payment by CMS, the state-specific and (if requested) the 5% national sample data files described in Section 1.5 will be encrypted and prepared for delivery to the QE's point of contact listed on the DUA. The DUA number and data request specifications will be recorded and tracked using standard CCW operating procedures.

The QE will have the option of either downloading its **encrypted data** files via a secure file transfer mechanism or receiving the data via a USB hard drive (preference will be indicated on

the data request specifications worksheet). The data files will be encrypted prior to delivery using the PGP Command Line 9.0 with the Self-Decrypting Archive (SDA) method. This method builds a compressed, encrypted, password-protected file using a FIPS 140-1/140-2 approved AES256 cipher algorithm. For either delivery approach (download or hard drive shipment), the SDA decryption password will be sent electronically to the QE's point of contact listed on the DUA. Detailed decryption instructions will be provided with the data package. Confirmation of receipt of the data package and password will be requested from the recipient.

In addition to the flat files (claims and enrollment/demographic data), the data package will include file transfer summaries, SAS read-in programs, data dictionaries, tips on getting started, and other documentation. Each data package includes Buccaneer contact information for further technical assistance with using the CCW data files. While the Research Data Assistance Center (ResDAC) serves as the primary point of contact for CMS data requestors/users (http://www.resdac.org/QEMedicareData.asp), specific questions about the data files received from Buccaneer should be directed to Buccaneer's CCW staff. CCW staff will provide technical assistance to QEs through a variety of mechanisms, including:

- CCW website: http://www.ccwdata.org/
- CCW technical assistance email address: CMSdata@vangent.com
- Toll-free Helpline: 1-866-766-1915

The CCW website offers several resources for QEs. These include summary statistics for comparative analysis, data dictionaries for each file type, user guides, technical papers on producing prevalence rates, and other analytical guidance documentation.

ResDAC also offers CMS data user workshops for both beginner and more advanced Medicare data users. ResDAC will also assist the QEs in submitting their data request to CMS, including helping QEs confirm their estimated data costs. In addition, QEs with specific Medicare data questions or issues regarding potential data errors should contact ResDAC for guidance.

- ResDAC workshops: http://www.resdac.org/Training/workshops.asp
- ResDAC contact email: resdac@umn.edu
- Toll-Free Helpline: 1-888-9RESDAC (1-888-973-7322)

2.14 HOW TO REPORT CHANGES

2.14.1 Changes Impacting Publicly Reported Performance Information

Once approved as a qualified entity, a QE may wish to modify its program operations, which may affect its public reporting of performance information using Medicare data. As stated in the Final Rule, it is not the intention of the QECP to limit an entity's ability to change or adapt its business plan once it has been approved as a qualified entity. However, QEs are required to notify CMS about certain changes to their program. The 2012 Operations Manual Update (to be released during the second quarter of 2012) will provide additional clarification about QE

responsibilities for reporting program changes (e.g., changes to selected measures, changes to report prototypes). QEs will be required to incorporate and adhere to these requirements once the annual update is released.

2.14.2 Governance Changes

A QE that experiences changes in governance, such as a merger, acquisition, or consolidation (MAC), must submit written notice of such action within 30 calendar days following the merger, acquisition, or consolidation date. The written notice should be sent to the following address:

IMPAQ International, LLC
10420 Little Patuxent Parkway
Suite 300
Columbia, MD 21044
Attention: Qualified Entity Certification Program for Medicare Data (QECP)

Upon receipt of a notice of a change in governance, the QECP team will evaluate the transaction's impact on certification status and compliance with program requirements. The evaluation will consider any changes in infrastructure, data sources, security, and general expertise related to the certification of the original entity. The entity will be notified of the outcome of this evaluation.

2.15 MAINTAINING AND LOSING CERTIFICATION STATUS

2.15.1 Expiration and Renewal

QE status is valid for 3 years from the date of notification of CMS approval. The QE must submit data requests and fees to receive quarterly updates of Medicare data until the last 6 months of its qualification period. At that time, the entity must re-apply to QECP and undergo another review to continue receiving data.

2.15.2 Suspension and Termination

Upon notification that the applicant has received the requested data, the evaluation, monitoring, and oversight activities are scheduled. Activities include further review of program adherence, the data corrections process, measure implementation, public reporting formats and data protection, and systems security protocols. In this phase of the evaluation process a QE may have its certification temporarily suspended or terminated if it is no longer compliant with program requirements.

2.15.3 Reconsideration

As stated in the Final Rule (§ 401.711), QEs are required to notify CMS prior to updating plans previously reviewed as part of the application process if these plans would change proposed measures, prototype reports, public reports, data sources, or data volume. CMS may reconsider the previously issued certification if the applicant is no longer compliant based on the updated plans.

2.15.4 Voluntary Forfeiture

The Final Rule (§ 401.721) notes that QEs may voluntarily terminate their agreement with CMS once they have entered the evaluation, monitoring, and oversight phase of the program. If a QE determines that this is the most appropriate course, it must agree to immediately destroy or return to CMS the Medicare data that it received under the program. Fees paid to CMS by the QE will not be reimbursed.

2.15.5 Consequences for QEs with Negative Findings/Non-Compliance

At any time during the evaluation, monitoring, and oversight phase of the QECP, the QECP team may determine that the QE is no longer in compliance and is at risk for suspension, termination, reconsideration, or voluntary forfeiture. The QECP team will identify non-compliance and notify the QE to establish a corrective action plan. If remediation is not possible, the QE is subject to the consequences outlined in the Final Rule regarding termination (§ 401.721), in which CMS terminates the agreement with the QE and the QE must immediately destroy or return to CMS the Medicare data that it received under the program. Fees paid to CMS by the QE will not be reimbursed.

2012 OPERATIONS MANUAL

SECTION 3. MINIMUM REQUIREMENTS

3.0 INTRODUCTION TO QECP MINIMUM REQUIREMENTS

The 8 standards and 24 elements derived from the Final Rule, against which entities will be evaluated, are presented in this section. Each element describes the **assessment** to be performed by reviewers in evaluating an application, and the **documentation** that entities must submit for evaluation. Each element may be evaluated by more than one assessment. To meet the requirements for a single element, entities must comply with all assessments. Lack of compliance with any assessment may result in an entity's inability to receive Medicare data for performance measurement.

During the application submission process, entities are required to self-assess their ability to meet QECP minimum requirements. Since the application process is extensive and there are limits to the number of times an entity may apply for QE certification during a 12-month period, entities are encouraged to carefully evaluate their ability to meet the minimum requirements set forth by CMS in the Final Rule (42 CFR, Part 401, Subpart G) *prior to* submitting an application.

Exhibit 2 below defines the components of the minimum requirements against which entities will be evaluated.

Exhibit 2: Components of the Minimum Requirements

Component	Description
Standard	An area for review that defines the program requirements at the highest level. The standard includes intent, elements, assessments, and evidence.
Intent	A brief description of the importance of the standard.
Element	The component of a standard that is scored/reviewed and provides details about performance expectations. Each element within a standard is evaluated to determine the degree to which the entity has met the requirements of the standard.
Assessment	The component(s) of an element that the entity must demonstrate to meet the minimum requirements for each element in order to receive approval for the element. Several assessments may be required for a single element; assessments reflect an entity's degree of compliance with an element.
Evidence	An item that is submitted to demonstrate compliance with an element. For example, an element may require the entity to demonstrate that a specific document includes evidence of plans or experience. The evidence allows reviewers to determine whether the entity has met the assessment.

All information presented in Sections 3.1 through 3.8 below is also included in Section 4 of the paper-based QE application form (Appendix B).

3.1 STANDARD 1 – APPLICANT PROFILE

Intent: A prospective QE must provide information about its organization and structure, the types of providers and suppliers it intends to evaluate, the geographic areas for which it intends to report data, and its ability to meet financial requirements of the program.

Element 1A: Define applicant organization

Assessment: Applicant is a legally recognized "lead" entity, accountable to CMS for the receipt of Medicare data, with clear contractual relationships identified and documented between entities (when applicable) that make it possible for the applicant to meet the QECP standards.

Evidence: The applicant's incorporation, type of organization, and licensure, if applicable. Contractors or member organizations working with the lead entity in support of their QECP activities must also include incorporation, type of organization, and licensure information as well as evidence of a contractual relationship between the lead and other entities that includes breach of contract liability with potential for collecting damages for failure to perform.

Element 1B: Identify the geographic areas that applicant's reports will cover

Assessment: Applicant defines the geographic area in which performance reporting will incorporate the Medicare data.

Evidence:

1. Description of geographic area(s) by state for which the applicant requests Medicare data. If a 5% national sample is requested, a justification for the request must be included.
2. Description of geographic area(s) by state for which the applicant has claims data from another payer source(s).

Element 1C: Identify the types of providers or suppliers whose performance the applicant intends to assess using Medicare data

Assessment: Applicant lists the types of providers and suppliers for which it intends to evaluate performance using Medicare and other claims data.

Evidence: List of types of providers and suppliers to be covered in each geographic area report that uses Medicare data. The types of providers and suppliers must be those that submit claims, and are paid, for Medicare-covered services and those for which the applicant has at least one additional source of claims data. The following is a list of possible provider types as defined by the Social Security Act:

(a) Physicians
(b) Other health care practitioners
(c) Hospitals
(d) Critical access hospitals
(e) Skilled nursing facilities
(f) Comprehensive outpatient rehabilitation facilities
(g) Home health agencies
(h) Hospice programs
(i) Other facilities or entities that furnish items or services

Element 1D: Show ability to cover the costs of performing the required functions of a qualified entity

Assessment: Applicant's business model is projected to cover the cost of public reporting, both the cost of the data and the cost of developing the reports.

Evidence: Documentation of a program budget reviewed and, approved, and signed by the applicant's senior executives. Evidence must come from the applicant, not from a member organization or contractor.

3.2 STANDARD 2 – DATA SOURCES

Intent: A prospective QE must provide evidence of the ability to combine claims data from other sources to calculate performance reports.

Element 2A: Obtain claims data from at least one other payer source to combine with Medicare Parts A and B claims data, and Part D drug event data

Assessment: For the geographic areas identified in Element 1B and for providers and suppliers identified in Element 1C, applicant possesses claims data from at least one other source; however, obtaining claims data from two or more sources is preferable.

If the applicant does not possess other claims data at the time of application, see Section 2.2 and Appendix C for instructions on how to apply for a qualified-conditional certification.

Evidence: An attestation from the entities from which the applicant obtains claims data that will be combined with the Medicare data. The attestation should include geographic area and types of providers and suppliers included in the data shared with the prospective QE.

Element 2B: Accurately combine Medicare claims data with claims data from other payer sources

Assessments:
1. Applicant accurately combines Medicare claims data with claims data from at least one other payer source.
2. Applicant demonstrates experience, generally 3 or more years, accurately combining claims data from different payer sources.

Evidence:
1. Documented process for combining claims data from multiple payers for the purposes of performance measurement. At a minimum, this must include the applicant's method for matching provider and supplier identifiers across different claims data sources.
2. Document(s) showing 3 years of experience aggregating claims data to produce at least two performance measures.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

3.3 STANDARD 3 – DATA SECURITY

Intent: A prospective QE must provide evidence of rigorous data privacy and security policies including enforcement mechanisms.

Element 3A (Administrative): Show ability to comply with Federal data security and privacy requirements, and document a process to follow those protocols

Assessment: Applicant has established systems and protocols to address the following security elements (as detailed in FIPS 200):
- Audit and Accountability
- Certification, Accreditation, and Security Assessments
- Incident Response, including notifying CMS and beneficiaries of inappropriate data access, violations of applicable Federal and state privacy and security laws and regulations for the preceding 10-year period (or, if the applicant has not been in

existence for 10 years, the length of time the applicant has been an organization), and any corrective actions taken to address the issues
- Planning
- Risk Assessment
- Compliance with applicable state laws regarding privacy and security

Evidence:

1. Current NIST Certification and Accreditation for compliance with FIPS 200 and SP 800-53 at the moderate impact level. If the applicant has not undergone this Certification and Accreditation process, it must produce documentation of the systems and protocols that meet this same threshold with respect to the security factors listed in Element 3A, which are further described below. If these systems and protocols do not meet the standards of FIPS 200 and SP 800-53 or have not yet been fully implemented, the applicant may be granted an opportunity to submit an agreed-upon plan of action and milestones (POA&M) and subsequently must demonstrate appropriate improvements to meet compliance.

   Audit and Accountability: Applicant must: (i) create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate information system activity; and (ii) ensure that the actions of individual information system users may be uniquely traced to those users so they can be held accountable for their actions.

   Certification, Accreditation, and Security Assessments: Applicant must (i) periodically assess the security controls in organizational information systems to determine if the controls are effective in their application; (ii) develop and implement plans of action designed to correct deficiencies and reduce or eliminate vulnerabilities in organizational information systems; (iii) authorize the operation of organizational information systems and any associated information system connections; and (iv) monitor information system security controls on an ongoing basis to ensure the continued effectiveness of the controls.

   Incident Response: Applicant must (i) establish an operational incident handling capability for organizational information systems that includes adequate preparation, detection, analysis, containment, recovery, and user response activities; and (ii) track, document, and report incidents to organizational officials and/or authorities.

   Planning: Applicant must develop, document, periodically update, and implement security plans for organizational information systems that describe the security controls in place or planned for the information systems and the rules of behavior for individuals accessing the information systems.

   Risk Assessment: Applicant must periodically assess the risk to organizational operations (including mission, functions, image, or reputation), organizational assets, and individuals, resulting from the operation of organizational information systems and the associated processing, storage, or transmission of organizational information.

Compliance with applicable state laws regarding privacy and security: Applicants, regardless of Certification and Accreditation status, must document compliance with applicable state laws regarding privacy and security.

2. All applicants, regardless of Certification and Accreditation status, must document all breaches of data security or privacy within the past 10 years (or the lifetime of the organization if that is less than 10 years).
3. All applicants, regardless of Certification and Accreditation status, must document the protocols and systems that will be implemented for transferring information to providers and suppliers as part of the requests for corrections/appeals process.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 3B (Technical): Identify system users and prequalification process for access to data

Assessment: Applicant has established systems and protocols to address the following security elements (as detailed in FIPS 200):

- Access Control
- Awareness and Training
- Configuration Management
- Identification and Authentication
- Personnel Security

Evidence: Current NIST Certification and Accreditation for compliance with FIPS 200 and SP 800-53 at the moderate impact level. If the applicant has not undergone this Certification and Accreditation process, it must produce documentation of the systems and protocols in place with respect to the security factors listed in Element 3B, and further described below. If these systems and protocols do not meet the standards of FIPS 200 and SP 800-53 or have not yet been fully implemented, the applicant may be granted an opportunity to submit an agreed-upon plan of action and milestones (POA&M) and subsequently demonstrate appropriate improvements to meet compliance.

Access Control: Applicant must limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems) and to the types of transactions and functions that authorized users are permitted to exercise.

Awareness and Training: Applicant must: (i) ensure that managers and users of organizational information systems are made aware of the security risks associated with their activities and of the applicable laws, Executive Orders, directives, policies, standards, instructions, regulations, or procedures related to the security of organizational information systems; and (ii) ensure that

organizational personnel are adequately trained to carry out their assigned information security-related duties and responsibilities.

Configuration Management: Applicant must: (i) establish and maintain baseline configurations and inventories of organizational information systems (including hardware, software, firmware, and documentation) throughout the respective system development life cycles; and (ii) establish and enforce security configuration settings for information technology products employed in organizational information systems.

Identification and Authentication: Applicant must identify information system users, processes acting on behalf of users, or devices and authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

Personnel Security: Applicant must: (i) ensure that individuals occupying positions of responsibility within organizations (including third-party service providers of services) are trustworthy and meet established security criteria for those positions; (ii) ensure that organizational information and information systems are protected during and after personnel actions such as terminations and transfers; and (iii) employ formal sanctions for personnel failing to comply with organizational security policies and procedures.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 3C (Physical): Identify processes and systems in place to protect the IT physical infrastructure

Assessment: Applicant has established systems and protocols to address the following security elements (as detailed in FIPS 200):

- Contingency Planning
- Maintenance
- Media Protection
- Physical and Environmental Protection
- System and Services Acquisition
- System and Communications Protection
- System and Information Integrity

Evidence: Current NIST Certification and Accreditation for compliance with FIPS 200 and SP 800-53 at the moderate impact level. If the applicant has not undergone this Certification and Accreditation process, it must produce documentation of the systems and protocols in place with respect to the security factors listed in Element 3C, and described further below. If these systems and protocols do not meet the standards of FIPS 200 and SP 800-53 or have not yet

been fully implemented, the applicant may be granted an opportunity to submit an agreed-upon plan of action and milestones (POA&M) and subsequently demonstrate appropriate improvements to meet compliance.

Contingency Planning: Applicant must establish, maintain, and effectively implement plans for emergency response, backup operations, and post-disaster recovery for organizational information systems to ensure the availability of critical information resources and continuity of operations in emergency situations.

Maintenance: Applicant must: (i) perform periodic and timely maintenance on organizational information systems; and (ii) provide effective controls on the tools, techniques, mechanisms, and personnel used to conduct information system maintenance.

Media Protection: Applicant must: (i) protect information system media, both paper and digital; (ii) limit access to information on information system media to authorized users; and (iii) sanitize or destroy information system media before disposal or release for reuse.

Physical and Environmental Protection: Applicant must: (i) limit physical access to information systems, equipment, and the respective operating environments to authorized individuals; (ii) protect the physical plant and support infrastructure for information systems; (iii) provide supporting utilities for information systems; (iv) protect information systems against environmental hazards; and (v) provide environmental controls in facilities containing information systems.

System and Services Acquisition: Applicant must: (i) allocate sufficient resources to adequately protect organizational information systems; (ii) employ system development life cycle processes that incorporate information security considerations; (iii) employ software usage and installation restrictions; and (iv) ensure that third-party providers employ adequate security measures to protect information, applications, and/or services outsourced from the organization.

System and Communications Protection: Applicant must: (i) monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems; and (ii) employ architectural designs, software development techniques, and systems engineering principles that promote effective information security within organizational information systems.

System and Information Integrity: Applicant must: (i) identify, report, and correct information and information system flaws in a timely manner; (ii) provide protection from malicious code at locations within organizational information systems; and (iii) monitor information system security alerts and advisories and take actions in response.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

3.4 STANDARD 4 – METHODOLOGY FOR MEASUREMENT AND ATTRIBUTION

Intent: A prospective QE must provide evidence of its ability to accurately calculate quality and efficiency, effectiveness, or resource use measures from claims data for measures it intends to calculate with Medicare data.

Element 4A: Follow measure specifications

Assessment: Applicant uses measure specifications accurately for selected measures, including numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

Evidence: For the measures listed in Elements 5A and 5B, the applicant must supply the measure specifications through a hyperlink to the original specification, a URL, or a copy of the specifications.

Element 4B: Use a defined and transparent method for attribution of patients and episodes

Assessments:

1. Applicant identifies an appropriate method to attribute a particular patient's services or episode to specific providers and suppliers.
2. Applicant demonstrates experience, generally 3 or more years, accurately attributing patient's services or episode to specific providers and suppliers.

Evidence:

1. Methodology paper or document defining how the applicant attributes patient services or episodes to specific providers or suppliers. If the attribution methods are different for different types of providers and suppliers (or measures), the applicant describes each methodology.
2. Methodology paper or document describing attribution approaches the applicant has defined and executed over the past 3 years. Note that if the attribution methodology has changed over the past 3 years, the applicant must provide a rationale for the change.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 4C: Set and follow requirements to establish statistical validity of measure results for quality measures

Assessments:

1. For reporting quality measures using Medicare data, applicant uses only measures with at least 30 observations, or the calculated confidence interval is at least 90%, or the measure reliability is at least 0.70.
2. Applicant demonstrates experience, generally 3 or more years, producing measures with statistical validity.

Evidence:

1. Methodology paper or document stating the applicant's minimum requirements for reporting a measure that incorporates any of the received Medicare data. This includes one of the following: minimum sample size (or denominator size) requirements, minimum calculated confidence interval, or minimum reliability score requirements.
2. For each measure for which the applicant intends to incorporate Medicare data, the applicant must submit one of the following: the anticipated sample size, the reliability score, or the confidence interval that will be used in reporting. Evidence supporting these statements must be submitted.
3. Document(s) showing the applicant's requirements for establishing statistical validity, together with examples of how the applicant has applied them over the past 3 years for at least two quality measures for which it intends to incorporate Medicare data. If any of the selected quality measures require the application of distinct or different statistical thresholds, then these must also be submitted.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 4D: Set and follow requirements to establish statistical validity of measure results for efficiency, effectiveness, and resource use measures

Assessments:

1. For selected efficiency, effectiveness, and resource use measures using Medicare data, applicant uses only measures for which reliability and validity is demonstrated.
2. For selected efficiency, effectiveness, and resource use measures using Medicare data that specify the use of a standardized payment or pricing approach, the specified standardized payment methodology is used.

3. Applicant demonstrates experience, generally 3 or more years, producing measures with statistical validity.

Applicants are only required to submit evidence for Element 4D if they select efficiency, effectiveness, or resource use measures to evaluate providers or suppliers.

Evidence:

1. Methodology paper that states the applicant's minimum requirements for reporting a measure with combined data. This includes the minimum calculated confidence interval or the reliability score.
2. For each measure for which the QE intends to incorporate Medicare data, the applicant must submit one of the following: the anticipated sample size, the reliability score, or the confidence interval that will be used in reporting. Evidence supporting these statements must be submitted.
3. Document(s) showing the applicant's requirements for establishing statistical validity, together with examples of how the applicant has applied them over the past 3 years for each selected type of measure (efficiency, effectiveness, and resource use) for which it intends to incorporate Medicare data. If any of the selected measures require the application of distinct or different statistical thresholds, then these must also be submitted.
4. Description of standard payment methodology for applicable measures.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 4E: Use appropriate methods to employ risk adjustment

Assessments:

1. Applicant provides a rationale for using, or not using, a risk adjustment method for each selected measure. Furthermore, the applicant provides a description of the risk adjustment method for each applicable measure.
2. Applicant demonstrates experience, generally 3 or more years, applying risk adjustment if any of the selected measures require a risk adjustment approach.

Applicants are only required to submit evidence for Element 4E if they select a measure that specifies a risk adjustment method.

Evidence:

1. Methodology paper indicating for each measure for which the applicant intends to use Medicare data:
    (a) How the applicant has determined whether risk adjustment is necessary
    (b) The explicit methodology to be used for risk adjustment, including any case-mix or severity adjustment

(c) A justification if the applicant determines that risk adjustment is not necessary

2. Document(s) showing consideration of risk adjustment, use of risk adjustment methodologies, and/or justification for not using risk adjustment over the past 3 years.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 4F: Use appropriate methods to handle outliers

Assessments:

1. Applicant describes its outlier method (i.e., how to identify and account for outliers) for each selected measure as applicable.
2. Applicant demonstrates experience, generally 3 or more years, applying relevant outlier methods, as applicable.

Evidence:

1. Methodology paper indicating for each measure for which the applicant intends to incorporate Medicare data:
   (a) Rationale for using, or not using, an outlier method
   (b) Detailed description of outlier method; specifically, how to identify outliers (e.g., more than 3 standard deviations from the mean) and how to account for them (e.g., truncation or removal of outlier)
2. Document(s) showing identification of outliers, use of outlier methods, or justification for not using outlier methods over the past 3 years, for each type of measure.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 4G: Use comparison groups when evaluating providers or suppliers compared to each other

Assessments:

1. Applicant defines comparison groups it intends to use to report results for each selected measure.
2. Applicant demonstrates experience, generally 3 or more years, selecting relevant comparison groups (i.e., peer groups) for selected measures.

Evidence:

1. Description of the comparison or peer groups used to evaluate performance for each measure selected. Peer group identification includes each type of provider and supplier to be reported on, including:
    (a) How the peer group was identified (external data source, provider-reported specialty, Tax ID number)
    (b) Defined algorithms to identify relevant peer groups for measurement
    (c) Geographic parameters to correctly compare providers to their peers

2. Document(s) showing the peer groups to which providers and suppliers have been assigned, and how peer groups have been defined, during the past 3 years.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 4H: Use benchmarks when evaluating providers

Assessments:

1. Applicant defines benchmarks it intends to use to report results for each selected measure.
2. Applicant demonstrates experience, generally 3 or more years, comparing measure results with benchmarks.

Evidence:

1. Description of the benchmark selection process and any performance standard that is used. The benchmark selection process includes:
    (a) How the benchmark is identified or estimated (external data source, current data set)
    (b) Type of benchmark (90th percentile, national average, regional average)
    (c) Geographic parameters to correctly identify the benchmark if relevant (provided region assignment uses regional benchmarks)
2. Document(s) showing the comparison of performance results of providers and suppliers with benchmarks during the past 3 years.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

3.5 STANDARD 5 – MEASURE SELECTION

Intent: A prospective QE must provide documentation for each selected standard or alternative measure used in public reporting to demonstrate its validity, reliability, responsiveness to consumer preferences, and applicability.

Element 5A: Use standard measures

Assessment: Applicant selects standard measures for which it intends to incorporate Medicare data.

Evidence: List of selected measures for performance reporting. A description of each measure including:

(a) Name of measure
(b) Name of measure steward/owner
(c) Measure description
(d) Type of provider or supplier to which the applicant will apply the measure
(e) Hyperlink, URL, or copy of the measure specification
(f) Rationale for selecting the measure, including the relationship of the measure to existing measurement efforts and the relevance to the proposed population in the proposed geographic area

Element 5B: Use approved alternative measures

Assessments:

1. Applicant proposes alternative measure for which it intends to incorporate Medicare data. Composite measures are considered alternative measures, even if they composite or combine standard measures, unless the standard measure itself is a composite.
2. Applicant demonstrates the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure, through consultation and agreement with stakeholders in applicant's community or through the notice and comment rulemaking process.

Applicants are only required to submit evidence for Element 5B if they select an alternative measure to evaluate providers or suppliers.

Evidence:

1. List of proposed selected alternative measures. A description of each measure including:
   (a) Name of measure
   (b) Name of measure steward/owner
   (c) Measure description

(d) Type of provider or supplier to which the applicant will apply the measure
(e) Hyperlink, URL, or copy of the measure specification
(f) Evidence that the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure
(g) Rationale for selecting the measure, including the relationship of the measure to existing measurement efforts and the relevance to the proposed population in the proposed geographic area
(h) Process to monitor and evaluate if new scientific evidence is released or a related standard measure is endorsed. If new evidence or a standard measure is available, the QE must notify CMS (QECP team) and submit all the new evidence. The QE must start using the new standard measure within 6 months or the QE can request, with supporting scientific documentation, approval to continue using the alternative measure.

2. Documentation of consultation and agreement with stakeholders in the applicant's community, together with a description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments supporting and opposing the measure or documentation of notice and comment rulemaking process approval.

3.6 STANDARD 6 – VERIFICATION PROCESS

Intent: A prospective QE must provide evidence of a continuous process to correct measurement errors and assess measure reliability.

Element 6A: Systematically evaluate accuracy of the measurement process and correct errors

Assessment: Applicant demonstrates experience, generally 3 or more years, defining and verifying its measurement and reporting processes, including the correction of errors and updating of performance reports

Evidence:

1. Internal verification, audit process, or software used to evaluate the accuracy of calculating performance measures from claims data
2. Name, credentials, and title of staff responsible for verifying the measurement process
3. Process for correcting errors
4. Process for updating reports to providers, suppliers, and consumers
5. Sample report generated by the validation process
6. If using an external vendor, documentation of agreement and/or purchase order of the software and/or systems vendor utilized in the applicant's validation process
7. Document(s) showing applicant has 3 years of experience in evaluating the accuracy of the measurement process and correcting errors covering all relevant areas.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

3.7 STANDARD 7 – REPORTING OF PERFORMANCE INFORMATION

Intent: A prospective QE must demonstrate substantial experience and expertise in the design and dissemination of performance reports, as well as the capacity and commitment to continuously improve the reporting process.

Element 7A: Design reporting for providers, suppliers, and the public

Assessments:

1. Applicant designs public reporting to be produced using Medicare data, including understandable descriptions of measures used.
2. Applicant plans dissemination of information to users at least annually.

Evidence:

1. List of types of providers and suppliers in each geographic area to be covered by performance reporting
2. Performance rating approach(es), including the measure results and statistical methods used to estimate a rating
3. Prototype or mock-up of reports, including all items of information for the providers and suppliers as they will be displayed, including level of reporting, as well as any rating approaches (such as number of stars) to display performance. The prototypes must clearly explain the performance results or ratings. All prototypes must be submitted if they are different (e.g., the provider or supplier prototype and the public report prototype). Prototypes must further demonstrate:
    (a) An indication, for each item reported, whether or not it is to be calculated in any part with Medicare data
    (b) An understandable description of the measures used to evaluate the performance of providers and suppliers so that consumers, providers and suppliers, health plans, researchers, and other stakeholders can assess performance reports
    (c) Intended reporting at the provider or supplier level, or at a higher, more aggregated level (consistent with measure specifications)
    (d) Intended display of measures in dispute (per provider)
4. Dissemination plans to inform all intended audiences of the existence of the performance reports, including how to locate them.

Element 7B: Improve reporting

Assessment: Applicant demonstrates experience, generally 3 or more years, designing and continuously improving public reporting on health care quality, efficiency, effectiveness, or resource use.

Evidence: Document(s) showing results of previous evaluation of reporting for the past 3 years, such as testing with users and use of evaluations to improve reporting.

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

3.8 STANDARD 8 – REQUESTS FOR CORRECTIONS/APPEALS

Intent: A prospective QE must provide evidence of implementing and maintaining an acceptable process for providers and suppliers identified in a report to review the report prior to publication, and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

Element 8A: Use corrections process

Assessment: Applicant has established a process to allow providers and suppliers to view reports confidentially, request data, and ask for correction of errors before the reports are made public.

Evidence: Process by which the applicant will share relevant information about anticipated public reporting on a provider or a supplier with that provider or supplier at least 60 business days prior to publicly reporting results. Applicant demonstrates experience, generally 3 or more years, including sharing:

(a) Selected measures on which the provider or supplier is being measured
(b) Rationale for use
(c) Measurement methodology
(d) Data specifications and limitations
(e) Measure results for the provider or supplier
(f) Anticipated date for publishing reports for the public
(g) Description of the ongoing process by which providers or suppliers may
    i. Request additional information or data
    ii. Request corrections or changes prior to public reporting

Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

Element 8B: Use secure transmission of beneficiary data

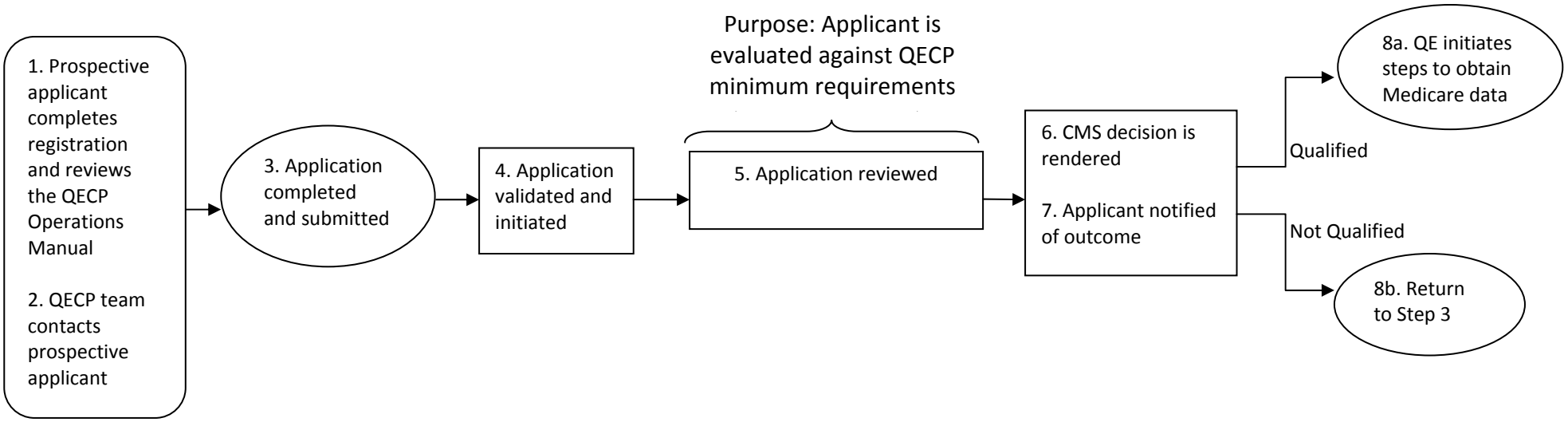
Assessment: Applicant has established a process that applies privacy and security protections to the release of beneficiary identifiers and claims data to providers or suppliers for the purposes of the requests for corrections/appeals process.

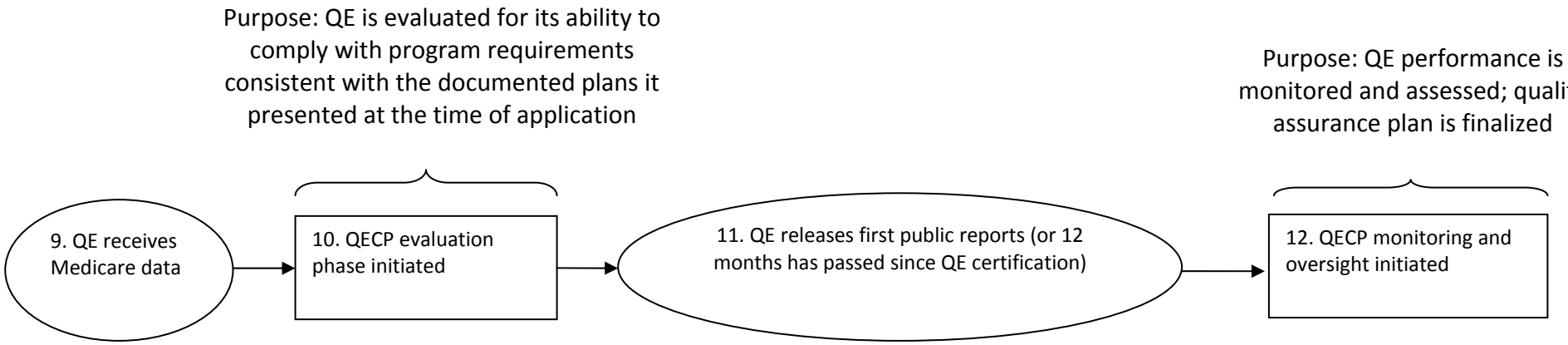
Evidence: Description of process ensuring that only the minimum necessary beneficiary identifiers and claims data will be disclosed in the event of a request by a provider or a supplier, including the method for secure transmission.

2012 OPERATIONS MANUAL

APPENDIX A. QECP PROCESS FLOW

APPENDIX A: QECP PROCESS FLOW





2012 OPERATIONS MANUAL

APPENDIX B. PAPER-BASED QE APPLICATION FORM

QUALIFIED ENTITY CERTIFICATION PROGRAM
FOR MEDICARE DATA

APPENDIX B: PAPER-BASED QE APPLICATION FORM

Date Application Submitted	

Date Application Received by CMS	

Section 1: General Information

Instructions: Please input the prospective applicant's information. The listed trade name and type of applicant should be for the lead applicant. Subcontractors or partners for this effort should be listed in the Member Organizations field.

Applicant's Trade Name/DBA	
Type of Applicant ☐ Profit Organization ☐ Non-Profit Organization ☐ Other *(describe)*	
Applicant's Employer ID Number	
Name(s) of Contractor(s) or Member Organization(s) *(Contact support@QEMedicareData.org to obtain further instructions to submit required contractor or member organization information)*	
Data Recipient's Name	

Data Requested ☐ Regional *(specify States)* ☐ National	

Section 2: Mailing Address

Instructions: The mailing address should be an address where mail correspondence about the application or program can be delivered.

Street Mailing Address _____

Suite/Mail Stop _____

City _____ State _____ ZIP Code _____

Phone _____ Fax _____

Website _____

Section 3: Contact Information

Chief Executive Officer (or other equivalent executive)

Instructions: Please provide the contact information for the CEO, or equivalent executive, who has the authority to oversee the entity's application and QECP responsibilities.

Prefix _____

First Name_____

Middle Initial _____

Last Name_____

Degree _____

E-mail Address _____

Street Mailing Address _____

Suite/Mail Stop _____

City _____ State _____ ZIP Code _____

Phone _____ Fax _____

Point of Contact for Application

Instructions: Please provide the contact information for the individual who will be the primary contact for day-to-day application and program correspondence.

Prefix _____

First Name_____

Middle Initial _____

Last Name_____

Degree _____

E-mail Address _____

Street Mailing Address _____

Suite/Mail Stop _____

City _____ State _____ ZIP Code _____

Phone _____ Fax _____

Section 4: Standards

Instructions: Please indicate whether the entity is capable of supplying information with regard to each element by checking the appropriate box (Yes, No, N/A). Using plain language, please provide explanations in the "explanation of self-assessment" comment box.

Entities are also required to submit supporting documentation to support their self-assessment and for the purposes of the minimum requirements review and assessment. Please list the name of the supporting document, its relevance to the element, and the pages within the document that prove such relevance. Additional supporting documentation may be listed in Section 6 of this application form. Refer to the accompanying QECP Operations Manual for complete program information.

STANDARD 1: APPLICANT PROFILE

Intent: A prospective QE must provide information about its organization and structure, the types of providers and suppliers it intends to evaluate, the geographic areas for which it intends to report data, and its ability to meet financial requirements of the program.

Element 1A: Define applicant organization	
Assessment:	**Self - assessment:**
Applicant is a legally recognized "lead" entity, accountable to CMS for the receipt of Medicare data, with clear contractual relationships identified and documented between entities (when applicable) that make it possible for the applicant to meet the QECP standards.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence:	
The applicant's incorporation, type of organization, and licensure, if applicable. Contractors or member organizations working with the lead entity in support of their QECP activities must also include incorporation, type of organization, and licensure information as well as evidence of a contractual relationship between the lead and other entities that includes breach of contract liability with potential for collecting damages for failure to perform.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Element 1B: Identify the geographic areas that applicant's reports will cover	
Assessment:	**Self - assessment:**
Applicant defines the geographic area in which performance reporting will incorporate the Medicare data.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence:	
1. Description of geographic area(s) by state for which the applicant requests Medicare data. If a 5% national sample is requested, a justification for the request must be included.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	
2. Description of geographic area(s) by state for which the applicant has claims data from another payer source(s).	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 1C: Identify the types of providers or suppliers whose performance the applicant intends to assess using Medicare data	
Assessment:	**Self - assessment:**
Applicant lists the types of providers and suppliers for which it intends to evaluate performance using Medicare and other claims data.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence:	
List of types of providers and suppliers to be covered in each geographic area report that uses Medicare data. The types of providers and suppliers must be those that submit claims, and are paid, for Medicare-covered services and those for which the applicant has at least one additional source of claims data. The following is a list of possible provider types as defined by the Social Security Act: (a) Physicians (b) Other health care practitioners (c) Hospitals (d) Critical access hospitals (e) Skilled nursing facilities (f) Comprehensive outpatient rehabilitation facilities (g) Home health agencies (h) Hospice programs (i) Other facilities or entities that furnish items or services	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 1D: Show ability to cover the costs of performing the required functions of a qualified entity	
Assessment:	**Self - assessment:**
Applicant's business model is projected to cover the cost of public reporting, both the cost of the data and the cost of developing the reports.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence:	
Documentation of a program budget reviewed and, approved, and signed by the applicant's senior executives. Evidence must come from the applicant, not from a member organization or contractor.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

STANDARD 2: DATA SOURCES

Intent: A prospective QE must provide evidence of the ability to combine claims data from other sources to calculate performance reports.

Element 2A: Obtain claims data from at least one other payer source to combine with Medicare Parts A and B claims data, and Part D drug event data	
Assessment:	**Self - assessment:**
For the geographic areas identified in Element 1B and for providers and suppliers identified in Element 1C, applicant possesses claims data from at least one other source; however, obtaining claims data from two or more sources is preferable.	☐ Yes ☐ No ☐ N/A
If the applicant does not possess other claims data at the time of application, see the QECP 2012 Operations Manual Section 2.2 and Appendix C for instructions on how to apply for a qualified-conditional certification.	
Explanation of Self-assessment:	
Evidence:	
An attestation from the entities from which the applicant obtains claims data that will be combined with the Medicare data. The attestation should include geographic area and types of providers and suppliers included in the data shared with the prospective QE.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 2B: Accurately combine Medicare claims data with claims data from other payer sources	
Assessments:	**Self - assessments:**
1. Applicant accurately combines Medicare claims data with claims data from at least one other payer source.	☐ Yes ☐ No
2. Applicant demonstrates experience, generally 3 or more years, accurately combining claims data from different payer sources.	☐ Yes ☐ No
Explanation of Self-assessments:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Documented process for combining claims data from multiple payers for the purposes of performance measurement. At a minimum, this must include the applicant's method for matching provider and supplier identifiers across different claims data sources.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

2. Document(s) showing 3 years of experience aggregating claims data to produce at least two performance measures.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

STANDARD 3: DATA SECURITY

Intent: A prospective QE must provide evidence of rigorous data privacy and security policies including enforcement mechanisms.

Element 3A (Administrative): Show ability to comply with Federal data security and privacy requirements, and document a process to follow those protocols	
Assessment:	**Self - assessment:**
Applicant has established systems and protocols to address the following security elements (as detailed in FIPS 200): ▪ Audit and Accountability ▪ Certification, Accreditation, and Security Assessments ▪ Incident Response, including notifying CMS and beneficiaries of inappropriate data access, violations of applicable Federal and state privacy and security laws and regulations for the preceding 10-year period (or, if the applicant has not been in existence for 10 years, the length of time the applicant has been an organization), and any corrective actions taken to address the issues ▪ Planning ▪ Risk Assessment ▪ Compliance with applicable state laws regarding privacy and security	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Current NIST Certification and Accreditation for compliance with FIPS 200 and SP 800-53 at the moderate impact level. If the applicant has not undergone this Certification and Accreditation process, it must produce documentation of the systems and protocols that meet this same threshold with respect to the security factors listed in Element 3A, which are further described below. If these systems and protocols do not meet the standards of FIPS 200 and SP 800-53 or have not yet been fully implemented, the applicant may be granted an opportunity to submit an agreed-upon plan of action and milestones (POA&M) and subsequently must demonstrate appropriate improvements to meet compliance. Audit and Accountability: Applicant must: (i) create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and	

reporting of unlawful, unauthorized, or inappropriate information system activity; and (ii) ensure that the actions of individual information system users may be uniquely traced to those users so they can be held accountable for their actions.

Certification, Accreditation, and Security Assessments: Applicant must (i) periodically assess the security controls in organizational information systems to determine if the controls are effective in their application; (ii) develop and implement plans of action designed to correct deficiencies and reduce or eliminate vulnerabilities in organizational information systems; (iii) authorize the operation of organizational information systems and any associated information system connections; and (iv) monitor information system security controls on an ongoing basis to ensure the continued effectiveness of the controls.

Incident Response: Applicant must (i) establish an operational incident handling capability for organizational information systems that includes adequate preparation, detection, analysis, containment, recovery, and user response activities; and (ii) track, document, and report incidents to organizational officials and/or authorities.

Planning: Applicant must develop, document, periodically update, and implement security plans for organizational information systems that describe the security controls in place or planned for the information systems and the rules of behavior for individuals accessing the information systems.

Risk Assessment: Applicant must periodically assess the risk to organizational operations (including mission, functions, image, or reputation), organizational assets, and individuals, resulting from the operation of organizational information systems and the associated processing, storage, or transmission of organizational information.

Compliance with applicable state laws regarding privacy and security: Applicants, regardless of Certification and Accreditation status, must document compliance with applicable state laws regarding privacy and security.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

2. All applicants, regardless of Certification and Accreditation status, must document all breaches of data security or privacy within the past 10 years (or the lifetime of the organization if that is less than 10 years).

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

3. All applicants, regardless of Certification and Accreditation status, must document the protocols and systems that will be implemented for transferring information to providers and suppliers as part of the requests for corrections/appeals process.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 3B (Technical): Identify system users and prequalification process for access to data	
Assessment:	**Self - assessment:**
Applicant has established systems and protocols to address the following security elements (as detailed in FIPS 200): ▪ Access Control ▪ Awareness and Training ▪ Configuration Management ▪ Identification and Authentication ▪ Personnel Security	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
Current NIST Certification and Accreditation for compliance with FIPS 200 and SP 800-53 at the moderate impact level. If the applicant has not undergone this Certification and Accreditation process, it must produce documentation of the systems and protocols in place with respect to the security factors listed in Element 3B, and further described below. If these systems and protocols do not meet the standards of FIPS 200 and SP 800-53 or have not yet been fully implemented, the applicant may be granted an opportunity to submit an agreed-upon plan of action and milestones (POA&M) and subsequently demonstrate appropriate improvements to meet compliance. Access Control: Applicant must limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems) and to the types of transactions and functions that authorized users are permitted to exercise. Awareness and Training: Applicant must: (i) ensure that managers and users of organizational information systems are made aware of the security risks associated with their activities and of the applicable laws, Executive Orders, directives, policies, standards, instructions, regulations, or procedures related to the security of organizational information systems; and (ii) ensure that organizational personnel are adequately trained to carry out their assigned information security-related duties and responsibilities. Configuration Management: Applicant must: (i) establish and maintain baseline configurations and inventories of organizational information systems (including hardware, software, firmware, and documentation) throughout the respective system development life cycles; and (ii) establish	

and enforce security configuration settings for information technology products employed in organizational information systems.

Identification and Authentication: Applicant must identify information system users, processes acting on behalf of users, or devices and authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

Personnel Security: Applicant must: (i) ensure that individuals occupying positions of responsibility within organizations (including third-party service providers of services) are trustworthy and meet established security criteria for those positions; (ii) ensure that organizational information and information systems are protected during and after personnel actions such as terminations and transfers; and (iii) employ formal sanctions for personnel failing to comply with organizational security policies and procedures.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 3C (Physical): Identify processes and systems in place to protect the IT physical infrastructure	
Assessment:	**Self - assessment:**
Applicant has established systems and protocols to address the following security elements (as detailed in FIPS 200): ▪ Contingency Planning ▪ Maintenance ▪ Media Protection ▪ Physical and Environmental Protection ▪ System and Services Acquisition ▪ System and Communications Protection ▪ System and Information Integrity	☐ Yes ☐ No
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
Current NIST Certification and Accreditation for compliance with FIPS 200 and SP 800-53 at the moderate impact level. If the applicant has not undergone this Certification and Accreditation process, it must produce documentation of the systems and protocols in place with respect to the security factors listed in Element 3C, and described further below. If these systems and protocols do not meet the standards of FIPS 200 and SP 800-53 or have not yet been fully implemented, the applicant may be granted an opportunity to submit an agreed-upon plan of action and milestones (POA&M) and subsequently demonstrate appropriate improvements to meet compliance. Contingency Planning: Applicant must establish, maintain, and effectively implement plans for emergency response, backup operations, and post-disaster recovery for organizational information systems to ensure the availability of critical information resources and continuity of operations in emergency situations. Maintenance: Applicant must: (i) perform periodic and timely maintenance on organizational information systems; and (ii) provide effective controls on the tools, techniques, mechanisms, and personnel used to conduct information system maintenance. Media Protection: Applicant must: (i) protect information system media, both paper and digital; (ii) limit access to information on information system media to authorized users; and (iii) sanitize or destroy information system media before disposal or release for reuse. Physical and Environmental Protection: Applicant must: (i) limit physical access to information systems, equipment, and the respective operating environments to authorized individuals; (ii) protect the physical plant and support infrastructure for information systems; (iii) provide supporting utilities for information systems; (iv) protect information systems against environmental hazards; and (v) provide environmental controls in facilities containing information systems. System and Services Acquisition: Applicant must: (i) allocate sufficient resources to adequately protect organizational information systems; (ii) employ system development life cycle processes	

that incorporate information security considerations; (iii) employ software usage and installation restrictions; and (iv) ensure that third-party providers employ adequate security measures to protect information, applications, and/or services outsourced from the organization.

System and Communications Protection: Applicant must: (i) monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems; and (ii) employ architectural designs, software development techniques, and systems engineering principles that promote effective information security within organizational information systems.

System and Information Integrity: Applicant must: (i) identify, report, and correct information and information system flaws in a timely manner; (ii) provide protection from malicious code at locations within organizational information systems; and (iii) monitor information system security alerts and advisories and take actions in response.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

STANDARD 4: METHODOLOGY FOR MEASUREMENT AND ATTRIBUTION

Intent: A prospective QE must provide evidence of its ability to accurately calculate quality and efficiency, effectiveness, or resource use measures from claims data for measures it intends to calculate with Medicare data.

Element 4A: Follow measure specifications	
Assessment:	**Self - assessment:**
Applicant uses measure specifications accurately for selected measures, including numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence:	
For the measures listed in Elements 5A and 5B, the applicant must supply the measure specifications through a hyperlink to the original specification, a URL, or a copy of the specifications.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Element 4B: Use a defined and transparent method for attribution of patients and episodes	
Assessments:	**Self - assessments:**
1. Applicant identifies an appropriate method to attribute a particular patient's services or episode to specific providers and suppliers.	☐ Yes ☐ No
2. Applicant demonstrates experience, generally 3 or more years, accurately attributing patient's services or episode to specific providers and suppliers.	☐ Yes ☐ No
Explanation of Self-assessments:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Methodology paper or document defining how the applicant attributes patient services or episodes to specific providers or suppliers. If the attribution methods are different for different types of providers and suppliers (or measures), the applicant describes each methodology.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

2. Methodology paper or document describing attribution approaches the applicant has defined and executed over the past 3 years. Note that if the attribution methodology has changed over the past 3 years, the applicant must provide a rationale for the change.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

Element 4C: Set and follow requirements to establish statistical validity of measure results for quality measures	
Assessments:	**Self - assessments:**
1. For reporting quality measures using Medicare data, applicant uses only measures with at least 30 observations, or the calculated confidence interval is at least 90%, or the measure reliability is at least 0.70.	☐ Yes ☐ No
2. Applicant demonstrates experience, generally 3 or more years, producing measures with statistical validity.	☐ Yes ☐ No
Explanation of Self-assessments:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Methodology paper or document stating the applicant's minimum requirements for reporting a measure that incorporates any of the received Medicare data. This includes one of the following: minimum sample size (or denominator size) requirements, minimum calculated confidence interval, or minimum reliability score requirements.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

2. For each measure for which the applicant intends to incorporate Medicare data, the applicant must submit one of the following: the anticipated sample size, the reliability score, or the confidence interval that will be used in reporting. Evidence supporting these statements must be submitted.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

3. Document(s) showing the applicant's requirements for establishing statistical validity, together with examples of how the applicant has applied them over the past 3 years for at least two quality measures for which it intends to incorporate Medicare data. If any of the selected quality measures require the application of distinct or different statistical thresholds, then these must also be submitted.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 4D: Set and follow requirements to establish statistical validity of measure results for efficiency, effectiveness, and resource use measures	
Assessments:	**Self - assessments:**
1. For selected efficiency, effectiveness, and resource use measures using Medicare data, applicant uses only measures for which reliability and validity is demonstrated.	☐ Yes ☐ No ☐ N/A
2. For selected efficiency, effectiveness, and resource use measures using Medicare data that specify the use of a standardized payment or pricing approach, the specified standardized payment methodology is used.	☐ Yes ☐ No ☐ N/A
3. Applicant demonstrates experience, generally 3 or more years, producing measures with statistical validity.	☐ Yes ☐ No ☐ N/A
Applicants are only required to submit evidence for Element 4D if they select efficiency, effectiveness, or resource use measures to evaluate providers or suppliers.	
Explanation of Self-assessments:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Methodology paper that states the applicant's minimum requirements for reporting a measure with combined data. This includes the minimum calculated confidence interval or the reliability score.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

2. For each measure for which the QE intends to incorporate Medicare data, the applicant must submit one of the following: the anticipated sample size, the reliability score, or the confidence interval that will be used in reporting. Evidence supporting these statements must be submitted.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

3. Document(s) showing the applicant's requirements for establishing statistical validity, together with examples of how the applicant has applied them over the past 3 years for each selected type of measure (efficiency, effectiveness, and resource use) for which it intends to incorporate Medicare data. If any of the selected measures require the application of distinct or different statistical thresholds, then these must also be submitted.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

4. Description of standard payment methodology for applicable measures.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

Element 4E: Use appropriate methods to employ risk adjustment	
Assessments:	**Self - assessments:**
1. Applicant provides a rationale for using, or not using, a risk adjustment method for each selected measure. Furthermore, the applicant provides a description of the risk adjustment method for each applicable measure.	☐ Yes ☐ No ☐ N/A
2. Applicant demonstrates experience, generally 3 or more years, applying risk adjustment if any of the selected measures require a risk adjustment approach.	☐ Yes ☐ No ☐ N/A
Applicants are only required to submit evidence for Element 4E if they select a measure(s) that specifies a risk adjustment method.	
Explanation of Self-assessments:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Methodology paper indicating for each measure for which the applicant intends to use Medicare data: (a) How the applicant has determined whether risk adjustment is necessary (b) The explicit methodology to be used for risk adjustment, including any case-mix or severity adjustment (c) A justification if the applicant determines that risk adjustment is not necessary	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

2. Document(s) showing consideration of risk adjustment, use of risk adjustment methodologies, and/or justification for not using risk adjustment over the past 3 years.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 4F: Use appropriate methods to handle outliers	
Assessments:	**Self - assessments:**
1. Applicant describes its outlier method (i.e., how to identify and account for outliers) for each selected measure as applicable.	☐ Yes ☐ No
2. Applicant demonstrates experience, generally 3 or more years, applying relevant outlier methods, as applicable.	☐ Yes ☐ No
Explanation of Self-assessments:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Methodology paper indicating for each measure with which the applicant intends to incorporate Medicare data: (a) Rationale to use, or not use, an outlier method (b) Detailed description of outlier method; specifically, how to identify outliers (e.g., more than 3 standard deviations from the mean) and how to account for them (e.g., truncation or removal of outlier).	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

2. Document(s) showing identification of outliers, use of outlier methods, or justification for not using outlier methods over the past 3 years, for each type of measure.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

Element 4G: Use comparison groups when evaluating providers or suppliers compared to each other	
Assessments:	**Self - assessments:**
1. Applicant defines comparison groups it intends to use to report results for each selected measure.	☐ Yes ☐ No
2. Applicant demonstrates experience, generally 3 or more years, selecting relevant comparison groups (i.e., peer groups) for selected measures.	☐ Yes ☐ No
Explanation of Self-assessments:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Description of the comparison or peer groups used to evaluate performance for each measure selected. Peer group identification includes each type of provider and supplier to be reported on, including: (a) How the peer group was identified (external data source, provider-reported specialty, Tax ID number) (b) Defined algorithms to identify relevant peer groups for measurement (c) Geographic parameters to correctly compare providers to their peers	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

2. Document(s) showing the peer groups to which providers and suppliers have been assigned, and how peer groups have been defined, during the past 3 years.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

Element 4H: Use benchmarks when evaluating providers	
Assessments:	**Self - assessments:**
1. Applicant defines benchmarks it intends to use to report results for each selected measure.	☐ Yes ☐ No
2. Applicant demonstrates experience, generally 3 or more years, comparing measure results with benchmarks.	☐ Yes ☐ No
Explanation of Self-assessments:	

Evidence:
Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.

1. Description of the benchmark selection process and any performance standard that is used. The benchmark selection process includes:
   (a) How the benchmark is identified or estimated (external data source, current data set)
   (b) Type of benchmark (90th percentile, national average, regional average,
   (c) Geographic parameters to correctly identify the benchmark if relevant (provided region assignment uses regional benchmarks)

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

2. Document(s) showing the comparison of performance results of providers and suppliers with benchmarks during the past 3 years.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

STANDARD 5: MEASURE SELECTION

Intent: A prospective QE must provide documentation for each selected standard or alternative measure used in public reporting to demonstrate its validity, reliability, responsiveness to consumer preferences, and applicability.

Element 5A: Use standard measures	
Assessment:	**Self - assessment:**
Applicant selects standard measures for which it intends to incorporate Medicare data.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence:	
List of selected measures for performance reporting. A description of each measure including: (a) Name of measure (b) Name of measure steward/owner (c) Measure description (d) Type of provider or supplier to which the applicant will apply the measure (e) Hyperlink, URL, or copy of the measure specification (f) Rationale for selecting the measure, including the relationship of the measure to existing measurement efforts and the relevance to the proposed population in the proposed geographic area	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 5B: Use approved alternative measures	
Assessments:	**Self - assessments:**
1. Applicant proposes alternative measure for which it intends to incorporate Medicare data. Composite measures are considered alternative measures, even if they composite or combine standard measures, unless the standard measure itself is a composite.	☐ Yes ☐ No ☐ N/A
2. Applicant demonstrates the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure, through consultation and agreement with stakeholders in applicant's community or through the notice and comment rulemaking process.	☐ Yes ☐ No ☐ N/A
Applicants are only required to submit evidence for Element 5B if they select an alternative measure to evaluate providers or suppliers.	
Explanation of Self-assessments:	
Evidence:	
1. List of proposed selected alternative measures. A description of each measure including: (a) Name of measure (b) Name of measure steward/owner (c) Measure description (d) Type of provider or supplier to which the applicant will apply the measure (e) Hyperlink, URL, or copy of the measure specification (f) Evidence that the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure (g) Rationale for selecting the measure, including the relationship of the measure to existing measurement efforts and the relevance to the proposed population in the proposed geographic area (h) Process to monitor and evaluate if new scientific evidence is released or a related standard measure is endorsed. If new evidence or a standard measure is available, the QE must notify CMS (QECP team) and submit all the new evidence. The QE must start using the new standard measure within 6 months or the QE can request, with supporting scientific documentation, approval to continue using the alternative measure.	

Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____
2. Documentation of consultation and agreement with stakeholders in the applicant's community, together with a description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments supporting and opposing the measure or documentation of notice and comment rulemaking process approval.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

STANDARD 6: VERIFICATION PROCESS

Intent: A prospective QE must provide evidence of a continuous process to correct measurement errors and assess measure reliability.

Element 6A: Systematically evaluate accuracy of the measurement process, and correct errors	
Assessment:	**Self - assessment:**
Applicant demonstrates experience, generally 3 or more years, defining and verifying its measurement and reporting processes, including the correction of errors and updating of performance reports.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
1. Internal verification, audit process, or software used to evaluate the accuracy of calculating performance measures from claims data.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

2. Name, credentials, and title of staff responsible for verifying the measurement process.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

3. Process for correcting errors.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

4. Process for updating reports to providers, suppliers, and consumers.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

5. Sample report generated by the validation process.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

6. If using an external vendor, documentation of agreement and/or purchase order of the software and/or systems vendor utilized in the applicant's validation process.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

7. Document(s) showing applicant has 3 years of experience in evaluating the accuracy of the measurement process and correcting errors covering all relevant areas.
Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

STANDARD 7: REPORTING OF PERFORMANCE INFORMATION

Intent: A prospective QE must demonstrate substantial experience and expertise in the design and dissemination of performance reports, as well as the capacity and commitment to continuously improve the reporting process.

Element 7A: Design reporting for providers, suppliers, and the public	
Assessments:	**Self - assessments:**
1. Applicant designs public reporting to be produced using Medicare data, including understandable descriptions of measures used.	☐ Yes ☐ No
2. Applicant plans dissemination of information to users at least annually.	☐ Yes ☐ No
Explanation of Self-assessments:	
Evidence:	
1. List of types of providers and suppliers in each geographic area to be covered by performance reporting.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

2. Performance rating approach(es), including the measure results and statistical methods used to estimate a rating.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

3. Prototype or mock-up of reports, including all items of information for the providers and suppliers as they will be displayed, including level of reporting, as well as any rating approaches (such as number of stars) to display performance. The prototypes must clearly explain the performance results or ratings. All prototypes must be submitted if they are different (e.g., the provider or supplier prototype and the public report prototype). Prototypes must further demonstrate:
    (a) An indication, for each item reported, whether or not it is to be calculated in any part with Medicare data
    (b) An understandable description of the measures used to evaluate the performance of providers and suppliers so that consumers, providers and suppliers, health plans, researchers, and other stakeholders can assess performance reports
    (c) Intended reporting at the provider or supplier level, or at a higher, more aggregated level (consistent with measure specifications)
    (d) Intended display of measures in dispute (per provider)

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

4. Dissemination plans to inform all intended audiences of the existence of the performance reports, including how to locate them.

Supporting Documentation:

Document 1
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 2
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Document 3
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

Element 7B: Improve reporting	
Assessment:	**Self - assessment:**
Applicant demonstrates experience, generally 3 or more years, designing and continuously improving public reporting on health care quality, efficiency, effectiveness, or resource use.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
Document(s) showing results of previous evaluation of reporting for the past 3 years, such as testing with users and use of evaluations to improve reporting.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

STANDARD 8: REQUESTS FOR CORRECTIONS/APPEALS

Intent: A prospective QE must provide evidence of implementing and maintaining an acceptable process for providers and suppliers identified in a report to review the report prior to publication and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

Element 8A: Use corrections process	
Assessment:	**Self - assessment:**
Applicant has established a process to allow providers and suppliers to view reports confidentially, request data, and ask for correction of errors before the reports are made public.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence: Evidence of experience submitted by the applicant may be the demonstrated experience of the applicant, of the applicant's contractor, or, if the applicant is a collaborative, of any member organization of the collaborative.	
Process by which the applicant will share relevant information about anticipated public reporting on a provider or a supplier with that provider or supplier at least 60 business days prior to publicly reporting results. Applicant demonstrates experience, generally 3 or more years, including sharing: (a) Selected measures on which the provider or supplier is being measured (b) Rationale for use (c) Measurement methodology (d) Data specifications and limitations (e) Measure results for the provider or supplier (f) Anticipated date for publishing reports for the public (g) Description of the ongoing process by which providers or suppliers may i. Request additional information or data ii. Request corrections or changes prior to public reporting	

Supporting Documentation:
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____

Element 8B: Use secure transmission of beneficiary data	
Assessment:	**Self - assessment:**
Applicant has established a process that applies privacy and security protections to the release of beneficiary identifiers and claims data to providers or suppliers for the purposes of the requests for corrections/appeals process.	☐ Yes ☐ No
Explanation of Self-assessment:	
Evidence:	
Description of process ensuring that only the minimum necessary beneficiary identifiers and claims data will be disclosed in the event of a request by a provider or a supplier, including the method for secure transmission.	
Supporting Documentation:	
Document 1 Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 2** Document Name: _____ Document Relevance: _____ Relevant Pages: _____ **Document 3** Document Name: _____ Document Relevance: _____ Relevant Pages: _____	

Section 5: Attestation

Instructions: Prior to an application being submitted as final, the contents of the application must be accompanied with a completed attestation from an individual at the entity authorized to attest to its accuracy and completion.

To the best of my knowledge and belief, all data in this application are true and correct, the document has been duly authorized by the governing body of the applicant, and the applicant will comply with the terms and conditions of the award and applicable Federal requirements awarded.

Authorized Representative's Name (printed) _____

Authorized Representative's Title (printed) _____

Signature_____ Date _____

Phone _____ Fax _____

Section 6: Additional Supporting Documentation

Instructions: Please describe all additional supporting documentation submitted in conjunction with this application that is not listed in Section 4.

1. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

2. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

3. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

4. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

5. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

6. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

7. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

8. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

9. Standard: _____
   Element: _____
   Document Name: _____
   Document Relevance: _____
   Relevant Pages: _____

10. Standard: _____
    Element: _____
    Document Name: _____
    Document Relevance: _____
    Relevant Pages: _____

11. Standard: _____
Element: _____
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

12. Standard: _____
Element: _____
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

13. Standard: _____
Element: _____
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

14. Standard: _____
Element: _____
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

15. Standard: _____
Element: _____
Document Name: _____
Document Relevance: _____
Relevant Pages: _____

2012 OPERATIONS MANUAL

APPENDIX C. QUALIFIED–CONDITIONAL STATUS

APPENDIX C: QUALIFIED-CONDITIONAL STATUS

What is Qualified-Conditional Status?

The Qualified-Conditional certification indicates that an entity is compliant with all the application standards except the requirement of access to other claims data sources (Standard 2, Element 2B). An applicant certified as Qualified-Conditional will have 180 days to obtain access to relevant and adequate additional claims data. Once the QE-Conditional entity obtains access to such data, it must submit documentation that the claims data from other sources which it intends to combine with the Medicare data received under this program address the methodological concerns regarding sample size and reliability. Thus, the QE-Conditional entity will also be required to submit additional documentation for Standard 4. The QECP review team will then reassess the application against both Standard 2 (Element 2A) and Standard 4 (Elements 4C and 4D).

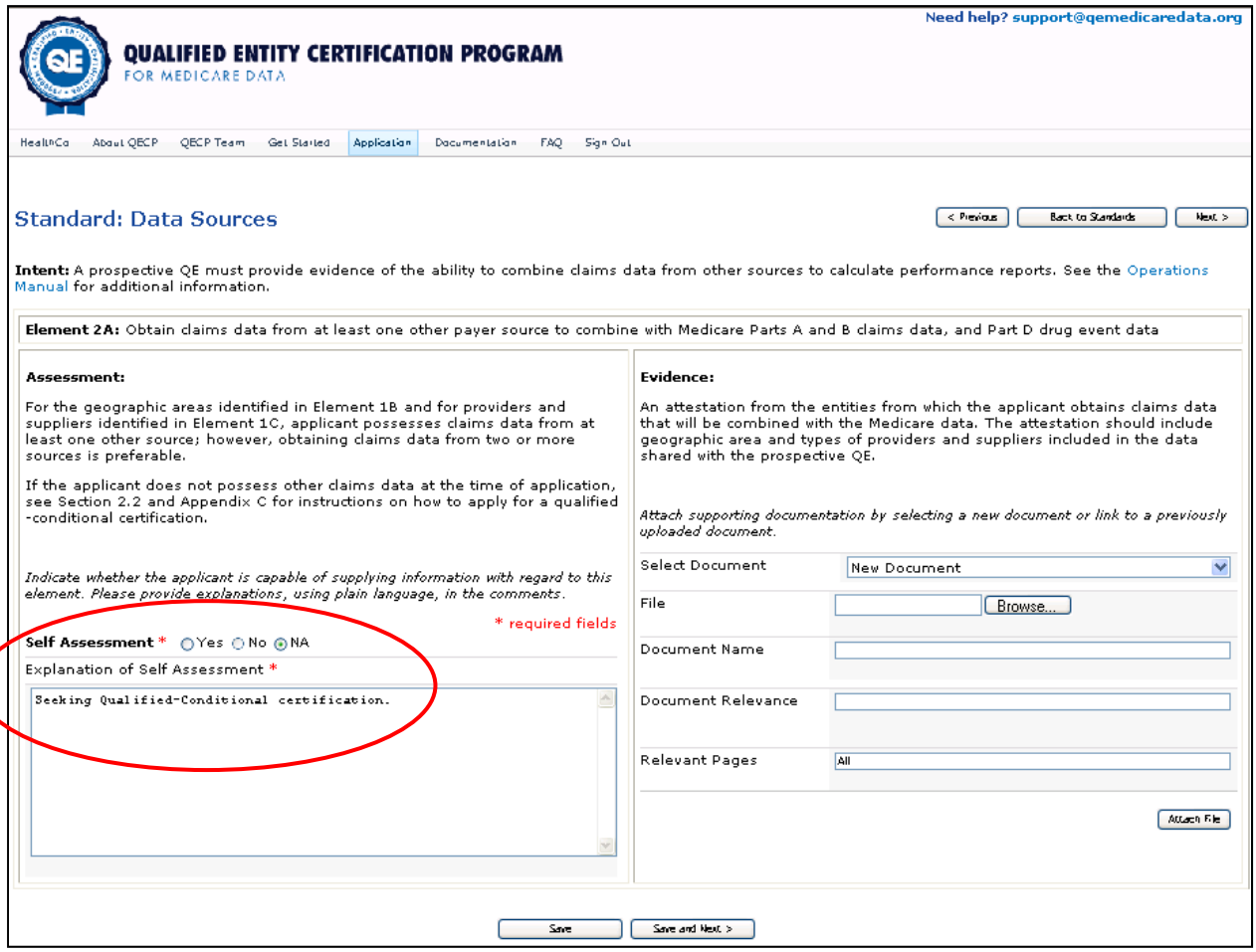
Upon successful completion of this final review, the entity will be recognized as a fully compliant QE.

Initial Review

Any entity may apply for Qualified-Conditional certification under the following conditions:

1. Requests Qualified-Conditional certification in the application (see Exhibit 3).
    a. In the application select N/A for Element 2A's self assessment.
    b. In Element 2A's self-assessment comment box, state "Seeking Qualified-Conditional certification."
2. Submits relevant evidence and demonstrates full compliance with all other elements (including Element 2B) and standards in the QECP Application.

Exhibit 3: How to Request a Qualified-Conditional Certification Review



After a review for conditional certification, CMS will render a decision. Key considerations of Qualified-Conditional certification are:

1. Entity will be deemed Qualified-Conditional after demonstrating full compliance with all other standards excluding Element 2A (the applicant must be fully compliant with Standard 2, Element 2B).
2. Qualified-Conditional status is valid for 180 days.
3. CMS will publicly report this status; entities will be sent a letter confirming their conditional certification status and may use it to secure another source of data.
4. Entities that are deemed Qualified-Conditional will not be able to receive any of the standardized Medicare data extracts.

An entity must obtain access to adequate and relevant claims data other than Medicare Parts A and B claims data and Part D PDE data to be considered for Qualified status (i.e., a qualified entity). If the entity does not obtain the additional claims data within 180 days of the Qualified-Conditional certification, the conditional certification expires and the entity will receive a final outcome of Not Qualified.

Final Review

An entity with Qualified-Conditional certification must submit requested evidence for Standard 2, Element 2A, and Standard 4, Elements 4C and 4D. The QECP review team will assess the entity's ability to meet these minimum requirements. The entity must demonstrate full compliance with all the standards at this time; previously assessed elements will not be re-assessed.

After the final review, CMS will issue a decision report with a status of Qualified or Not Qualified. Key considerations when certification status is changed from Qualified-Conditional to Qualified Entity are:

1. To be fully Qualified, the entity must be compliant with all standards of the QE application review.
2. The effective date of the outcome is the same as the effective date of Qualified-Conditional certification.
3. The QE expiration date is 3 years from the effective date of Qualified-Conditional certification.

Upon successful completion of this final review, the entity will be recognized as a fully compliant QE.

2012 OPERATIONS MANUAL

APPENDIX D. QECP PORTAL USER'S GUIDE

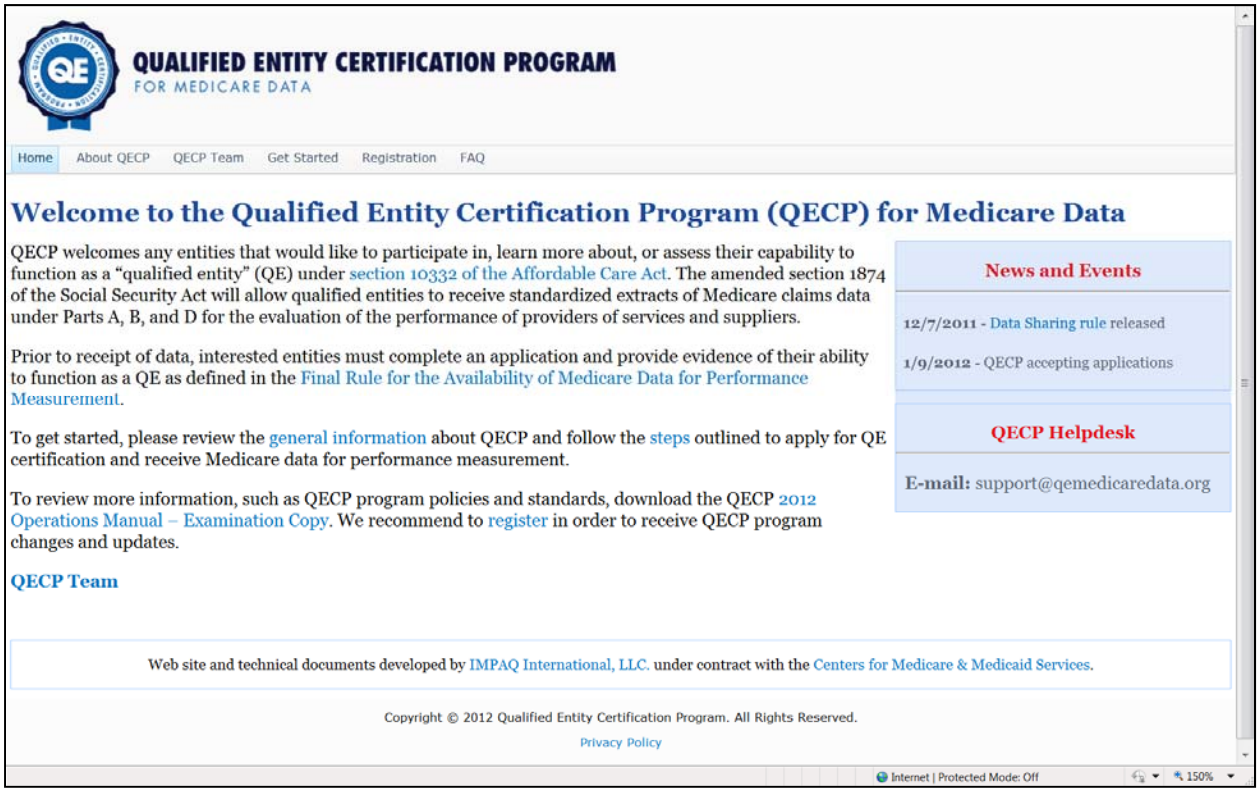
TABLE OF CONTENTS

1. ACCESSING THE QECP PORTAL SITE

Step 1a: Access the QECP Portal Home Page

To access the QECP Portal home page, visit www.QEMedicareData.org[1] (Figure 1).

Figure 1. QECP Portal Home Page



The home page provides an overview of the Qualified Entity Certification Program (QECP), a link to the *Final Rule for the Availability of Medicare Data for Performance Measurement*, news and events related to the QECP, and information about the QECP Helpdesk. You can contact the QECP Helpdesk via email at support@qemedicaredata.org or toll-free at 866-277-9966.

When contacting technical support via email, be sure to include the following information:

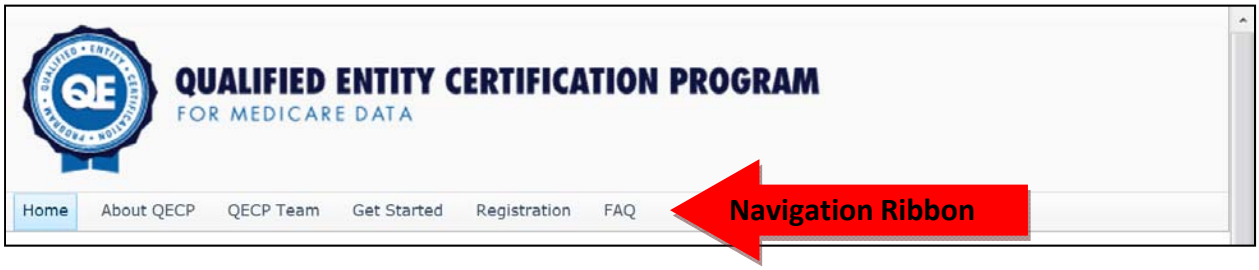
1) Your name
2) Entity with which you are affiliated
3) Email address
4) Phone number
5) Question or concern (please be as detailed as possible)

[1] The official www.qemedicaredata.org website contains the most up to date information. Screen shots within this guide are updated on a yearly basis only.

Once you submit an email to support@qemedicaredata.org, a technical support representative will contact you within 2 business days. This is the quickest method of contacting technical support because it allows us to direct your question to the most appropriate QECP team member.

You can navigate to other pages on the QECP Portal from the ribbon located below the logo. (Figure 2).

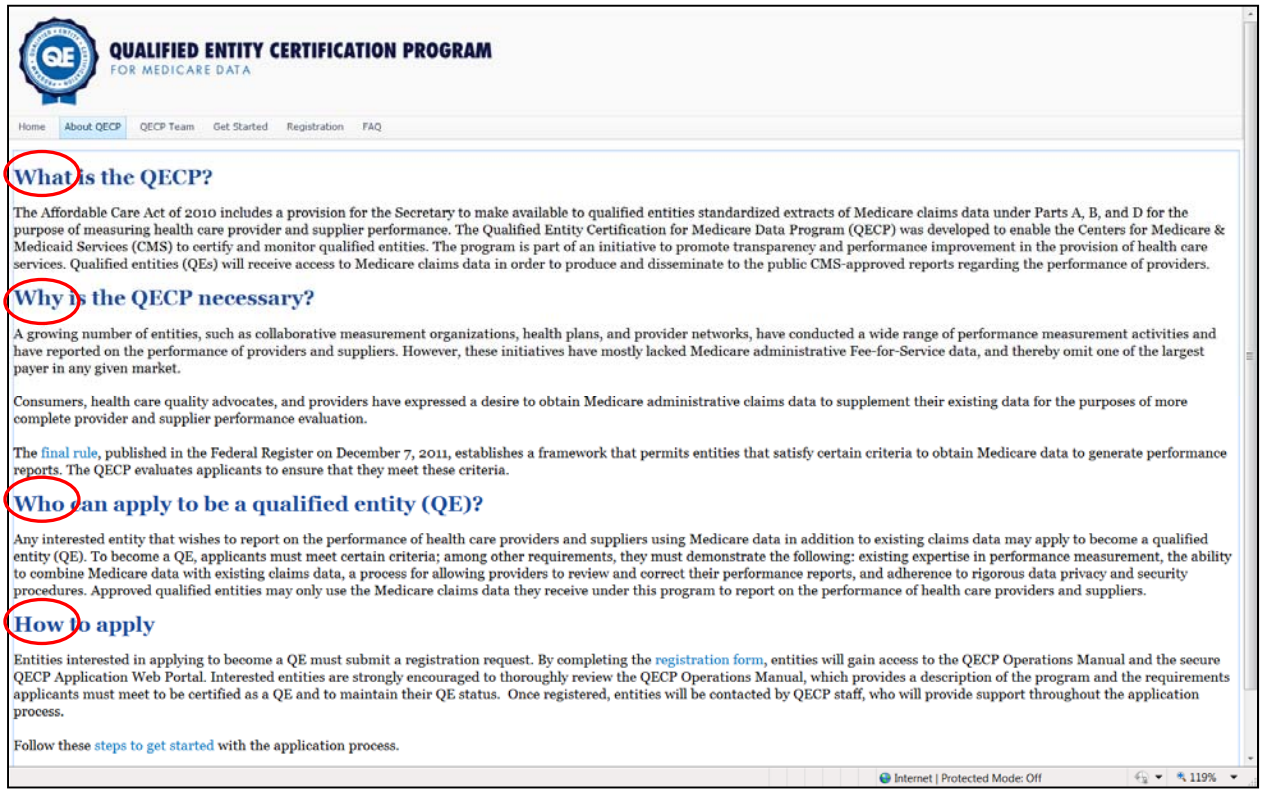
Figure 2. Navigating the Home Page



Step 1b: Visit the *About QECP* Page

The *About QECP* page provides information on **what** the QECP is, **why** QECP has been developed, **who** can apply to the program, and **how** you can apply (Figure 3).

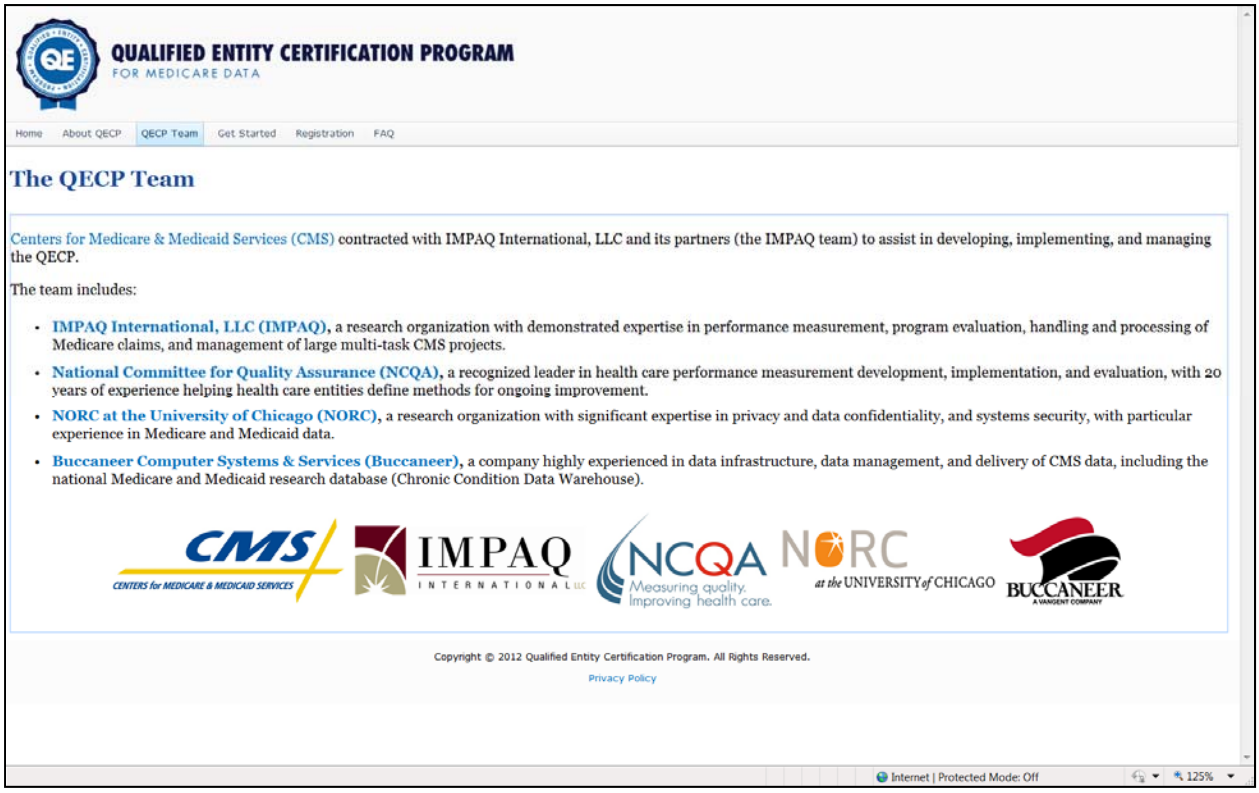
Figure 3. About QECP



Step 1c: Visit the QECP Team Page

The *QECP Team* page provides information on the organizations that have contracted with the Centers for Medicare & Medicaid Services (CMS) to assist in developing, implementing, and managing the QECP (Figure 4).

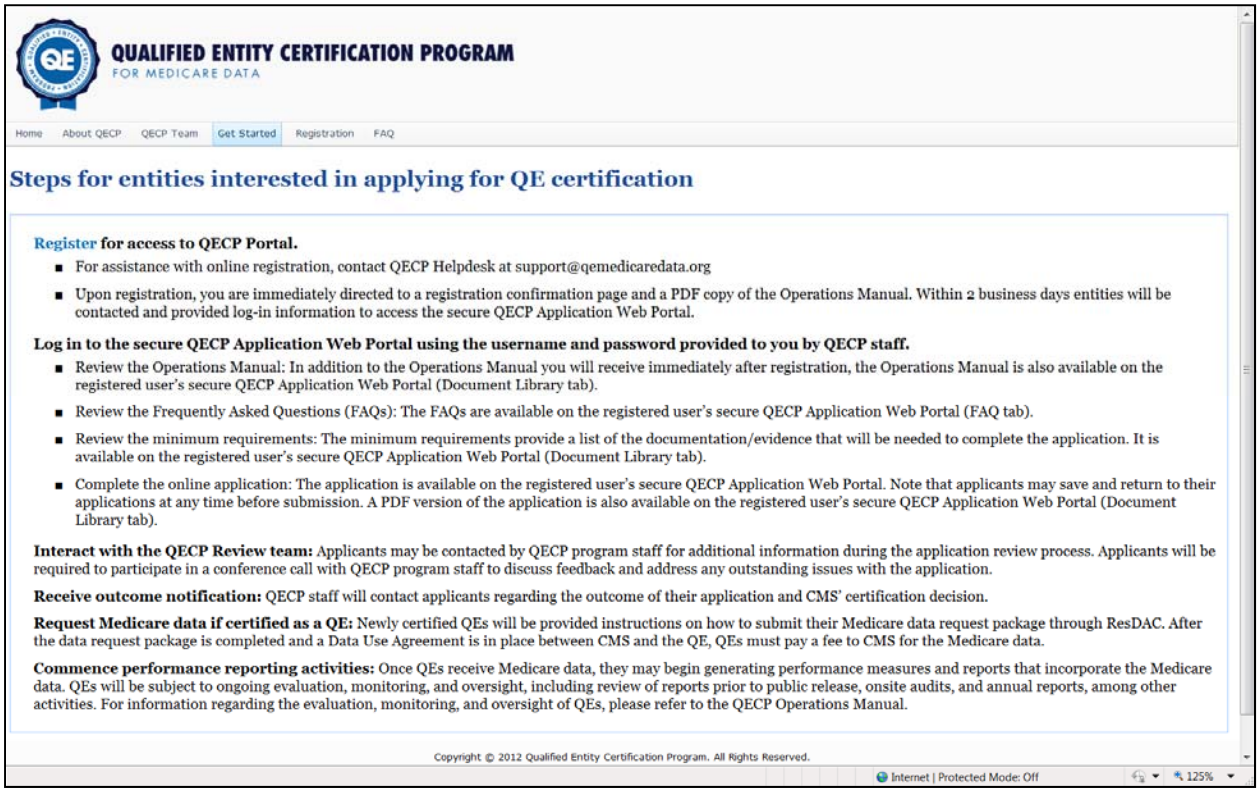
Figure 4. About the QECP Team



Step 1d: Access and Review the *Get Started* Page

The *Get Started* page provides information on the steps first time applicants should take to apply to the program (Figure 5). This information is a high-level overview to assist you in determining if you are interested in obtaining more information or would like to apply for certification as a qualified entity via the online application.

Figure 5. Steps for First-Time QE Applicants



2. COMPLETING THE REGISTRATION FORM

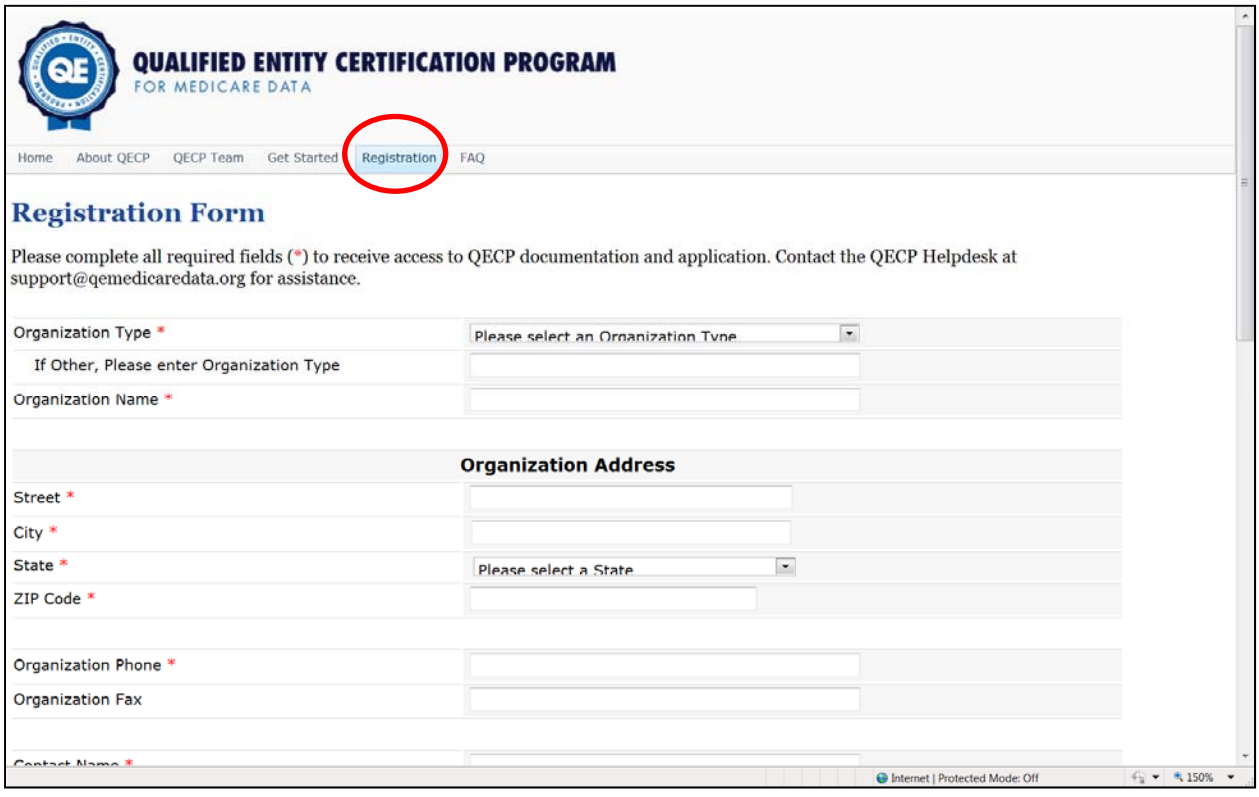
Step 2a: Access the Registration Form

To obtain online access to more information on the QECP, including the most up-to-date Operations Manual and the online application, you must complete a registration form. You may register even if you do not intend to apply for QE certification. For those not intending to apply, registration provides you access to the most up-to-date program information and communication. For those interested in applying, completing the registration form provides you access to the Operations Manual and the secure QECP Application Web Portal. Your information will not be shared and will be used solely to create a user profile and give you access to the secure area of the QECP Portal.

To complete the registration:

- Click the *Registration* tab from the navigation ribbon (Figure 6), or
- Email support@qemedicaredata.org for assistance.

Figure 6. Registration Form

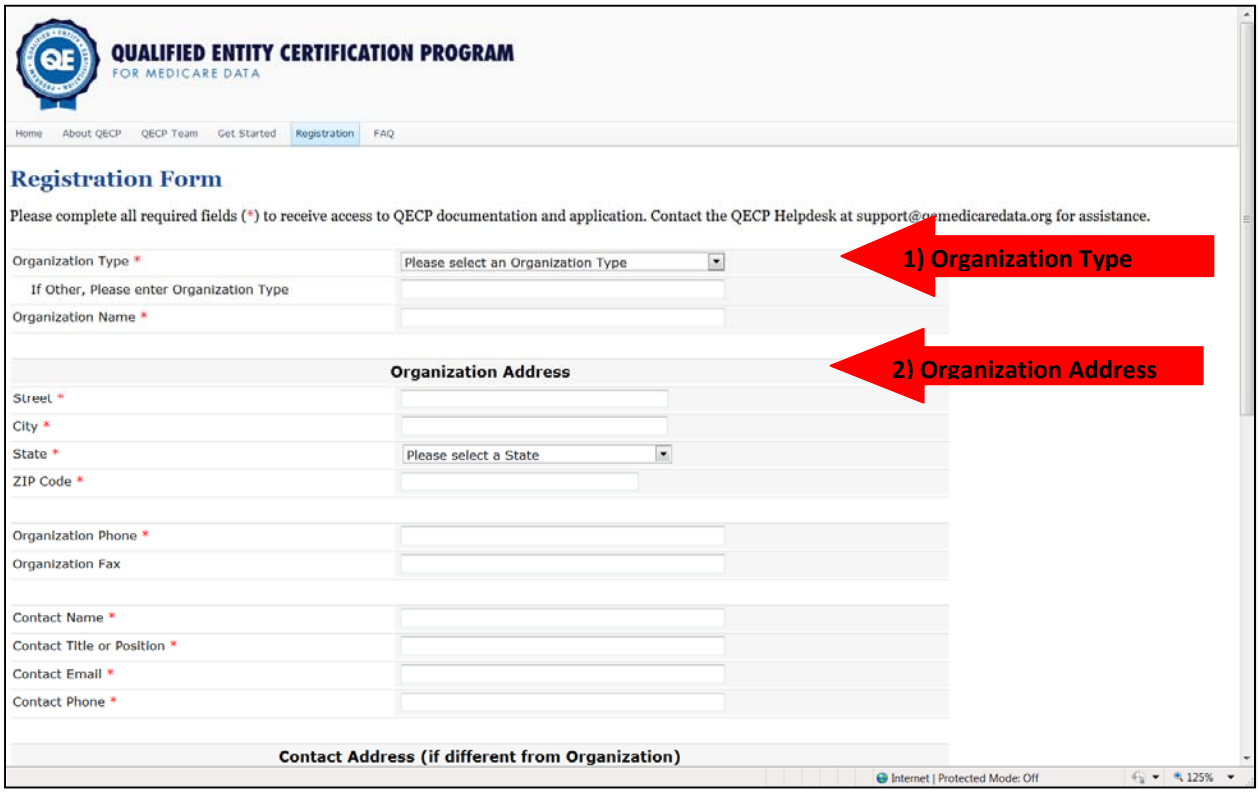


Step 2b: Complete Required Fields

All of the required fields are indicated with an asterisk. If you do not complete one of the required fields, you will not be able to submit your registration. The required fields include:

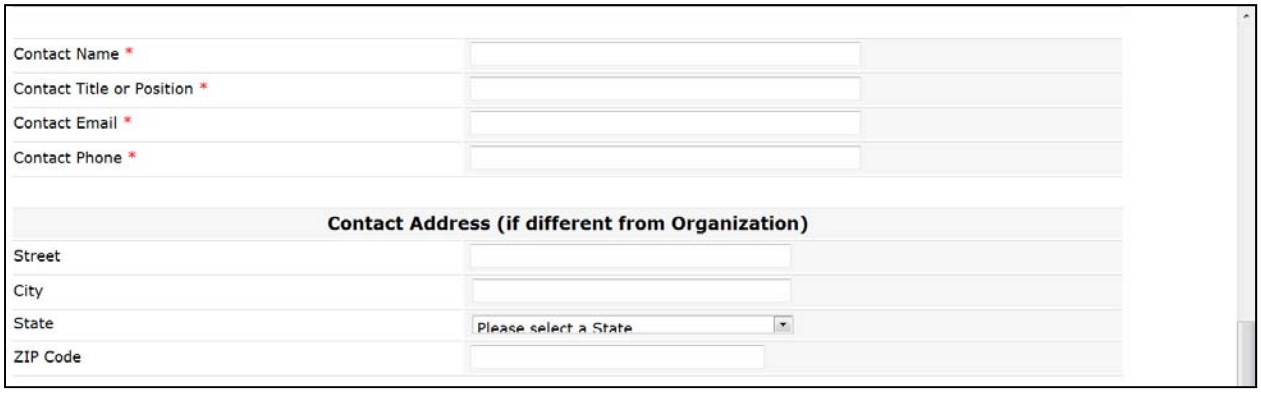
1) Organization Type (Figure 7)
   - If "other," please provide an explanation
2) Organization Address (Figure 7)
   - Street
   - City
   - State
   - Zip Code
   - Organization Phone
   - Organization Fax

Figure 7. Organization Type and Address



3) Contact Name and Information
   - Contact Name – This person will be the main point of contact throughout the application process (Figure 8).
   - Contact Title/Position
   - Contact Address (if different from organization address)
   - Contact Email
   - Contact Phone

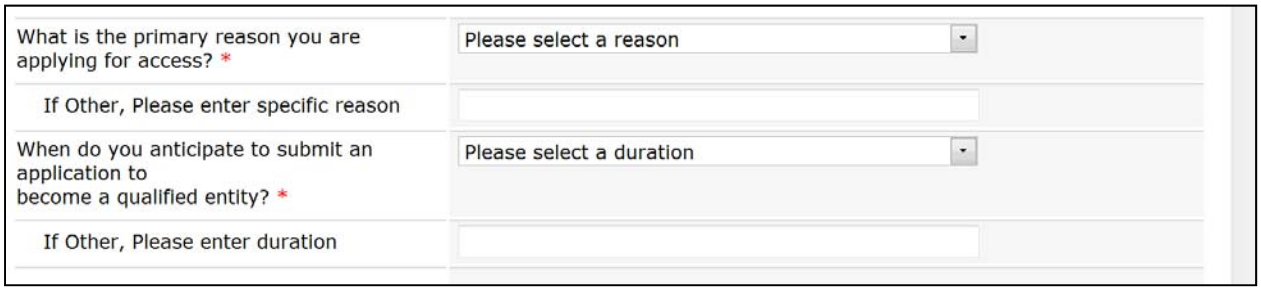
Figure 8. Contact Name and Information



4) Reason for Applying for Access (Figure 9)

- What is the primary reason you are applying for access?
  - If "other," please give specific reason.
- When do you anticipate submitting an application to become a qualified entity?
  - If "other," please estimate duration.

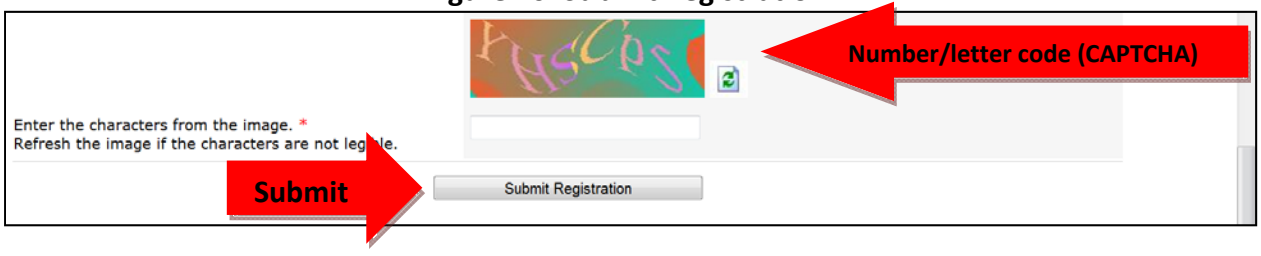
Figure 9. Reason for Applying for Access



Step 2c: Review and Submit

After completing the registration form, review it for accuracy. To submit the form, enter the listed number and letter code (CAPTCHA) in the box located underneath the CAPTCHA and then click **Submit Registration** (Figure 10).

Figure 10. Submit Registration



Step 2d: View Submission Completion Page

Once the registration form is submitted, a thank you page will appear, indicating that your registration form was successfully submitted (Figure 11). This page contains a link that enables you to download the Operations Manual. The Operations Manual provides detailed information about the QECP, policies and procedures, minimum requirements to become a qualified entity, and a sample application. Please begin reviewing the Operations Manual while your registration form is verified.

Figure 11. Registration Successful

3. RECEIVING YOUR USER PROFILE

Step 3a: Receive User Profile

Once your registration form has been verified, the contact you specified in the registration form will be contacted by a QECP program coordinator. For those entities that intend to apply to the QECP, you will also receive the login information (user profile). The user profile includes a unique user ID, password, and secure web address. This user profile gives you access to the online application and documentation library.

Step 3b: Request Additional User Profiles (optional)

During the verification of your registration form, a contact from your entity will be identified as the "Administrative User." Any additional users from your entity who complete the registration form must be verified by this Administrative User to gain access to your entity's online application.

4. ACCESSING THE SECURE QECP PORTAL

Prior to beginning the online application, prospective applicants should:

1) Review the operations manual
2) Review the sample application and required supporting documentation
3) Collect supporting documentation
4) Contact technical support for any questions or concerns

If you are unable to complete the application online, a hard-copy application is available and may be requested via email at support@qemedicaredata.org. However, it is recommended that you complete the application online to ensure completeness before submitting it and to speed the application processing procedure.

Step 4a: Login to Secure Application Site

After receiving your user profile, you will receive access to your entity's personal, secure site (Figure 12). Enter the user ID and password to enter the site, and click **Log In**.

Figure 12. Secure Application Site

The secure site allows you to access the online application and documentation pages as well as the pages on the previously viewed public site.

Step 4b: Review Available Documentation

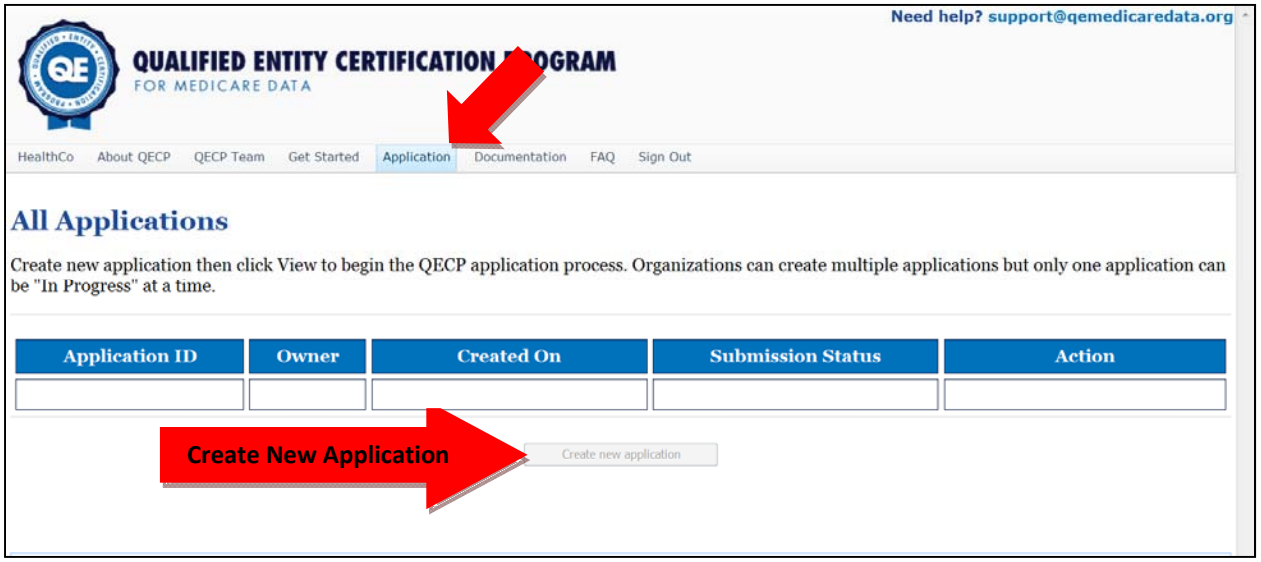
Before beginning the online application, you should visit the *Documentation* page and review the *2012 QECP Operations Manual* (Figure 13).

Figure 13. Documentation Library

Step 4c: Access Online Application

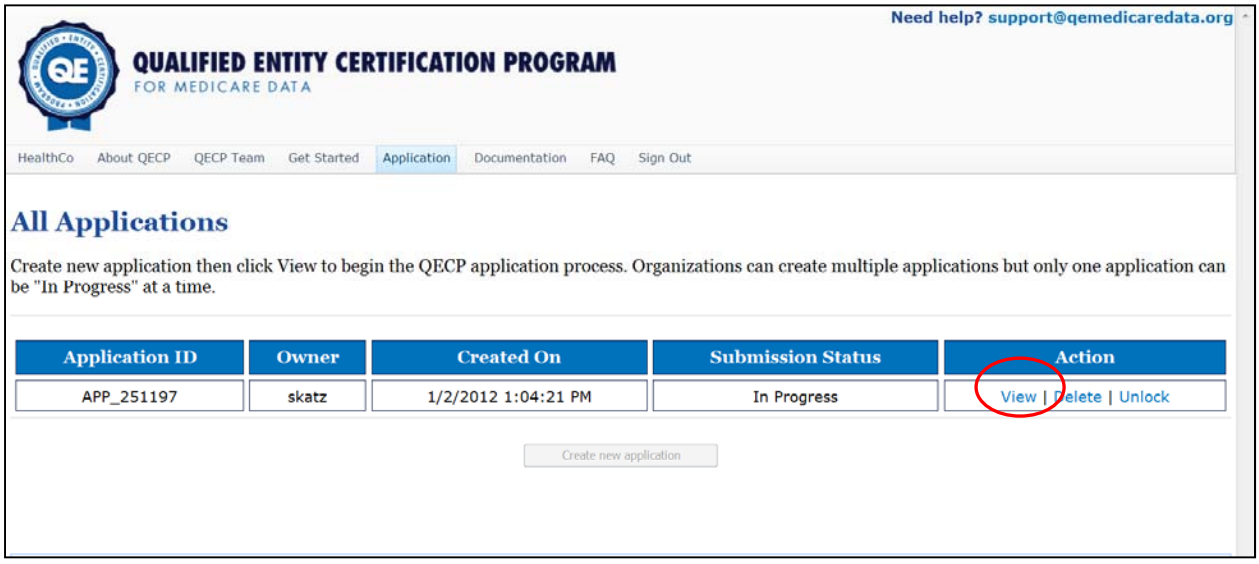
On the ribbon under the logo, you can access the *Application* page (Figure 14). Click **Create New Application** to begin.

Figure 14. Creating an Application



Your application will be assigned a unique application ID. To access the five sections of the application, click **View** under the **Action** column.

Figure 15. Application Created



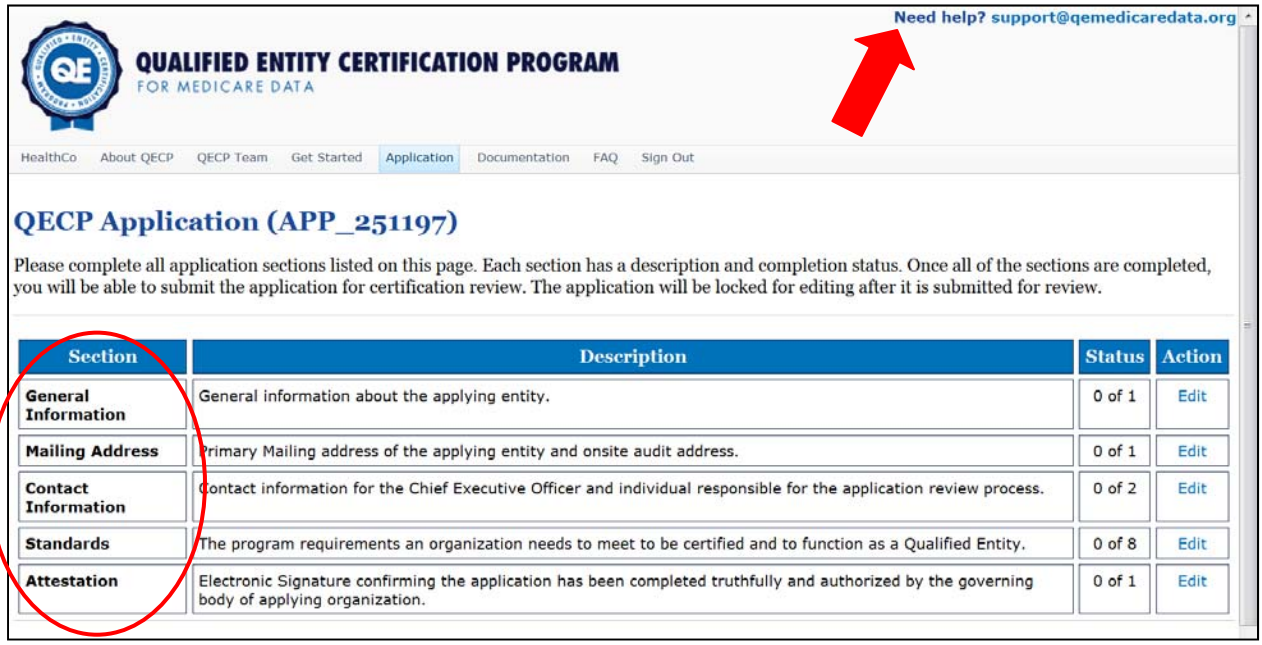
Step 4d: View Application Section Home Page

Once you click **View**, a screen will appear that shows the five application sections (Figure 16):

1) General Information
2) Mailing Address
3) Contact Information
4) Standards
5) Attestation

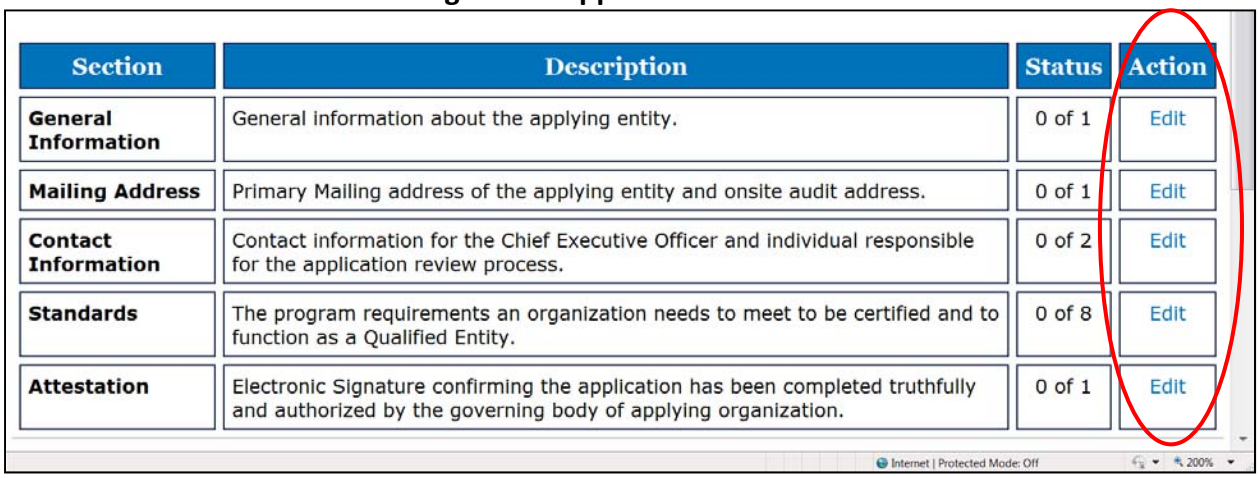
Technical support is available at any time during the application process. You can easily generate an email to support@qemedicaredata.org by clicking on **Need help?** at the top right corner (Figure 16).

Figure 16. Application Sections



To begin a section, click **Edit** under the **Action** column on the right-hand side of the screen (Figure 17). Each of the sections may be saved and returned to at a later time up until the application is submitted. Multiple users may access the same application simultaneously, but only information that has been saved is visible to the other users.

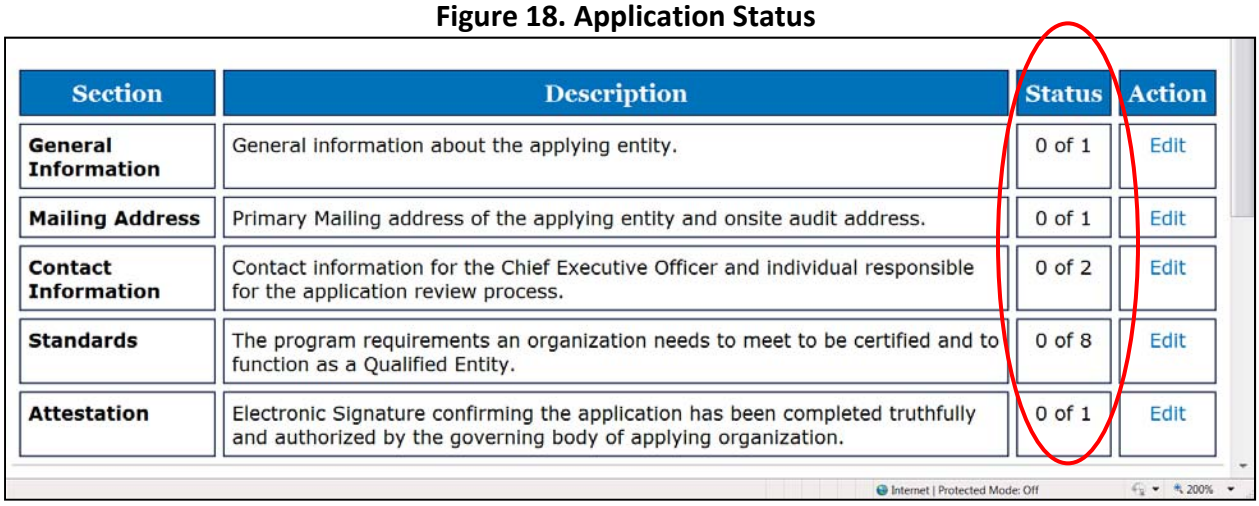
Figure 17. Application Sections



Section	Description	Status	Action
General Information	General information about the applying entity.	0 of 1	Edit
Mailing Address	Primary Mailing address of the applying entity and onsite audit address.	0 of 1	Edit
Contact Information	Contact information for the Chief Executive Officer and individual responsible for the application review process.	0 of 2	Edit
Standards	The program requirements an organization needs to meet to be certified and to function as a Qualified Entity.	0 of 8	Edit
Attestation	Electronic Signature confirming the application has been completed truthfully and authorized by the governing body of applying organization.	0 of 1	Edit

The progress of each section is tracked in the **Status** column (Figure 18).

Figure 18. Application Status

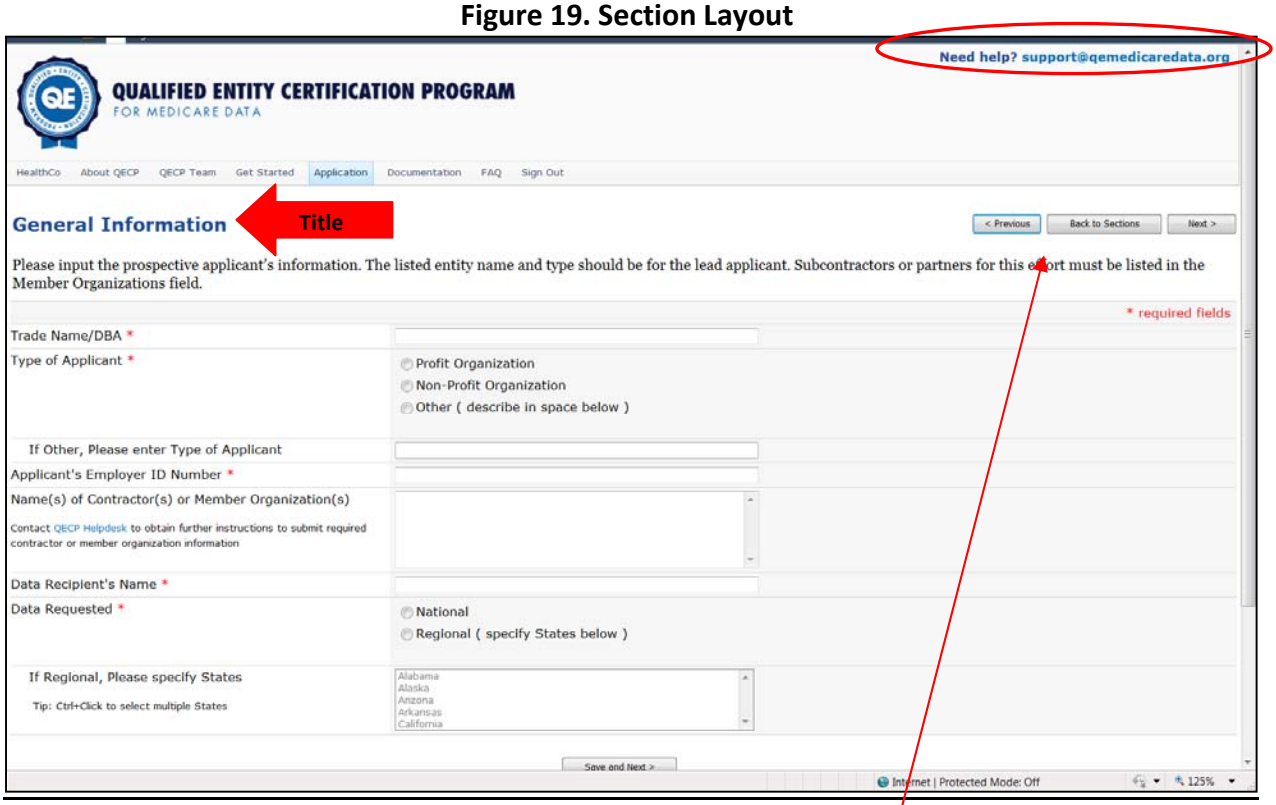


Section	Description	Status	Action
General Information	General information about the applying entity.	0 of 1	Edit
Mailing Address	Primary Mailing address of the applying entity and onsite audit address.	0 of 1	Edit
Contact Information	Contact information for the Chief Executive Officer and individual responsible for the application review process.	0 of 2	Edit
Standards	The program requirements an organization needs to meet to be certified and to function as a Qualified Entity.	0 of 8	Edit
Attestation	Electronic Signature confirming the application has been completed truthfully and authorized by the governing body of applying organization.	0 of 1	Edit

5. UNDERSTANDING THE APPLICATION SECTION LAYOUT

Each of the five application sections contains the same layout. The title of each section is displayed in the top left corner, and a brief description is provided underneath. You can obtain technical support at any time by clicking **Need help?** at the top right corner of the screen.

Figure 19. Section Layout



You can navigate from one section to the next by using the navigation buttons in the top right corner (Figure 20). The **Back to Sections** button returns you to the main application screen in Figure 16.

Figure 20. Navigation Controls

Before moving to the next section, make sure you click **Save and Next** at the bottom of the screen (Figure 21). If you navigate away from the page without saving, a warning will appear, asking for confirmation that you would like to leave the page without saving.

Figure 21. Save and Next

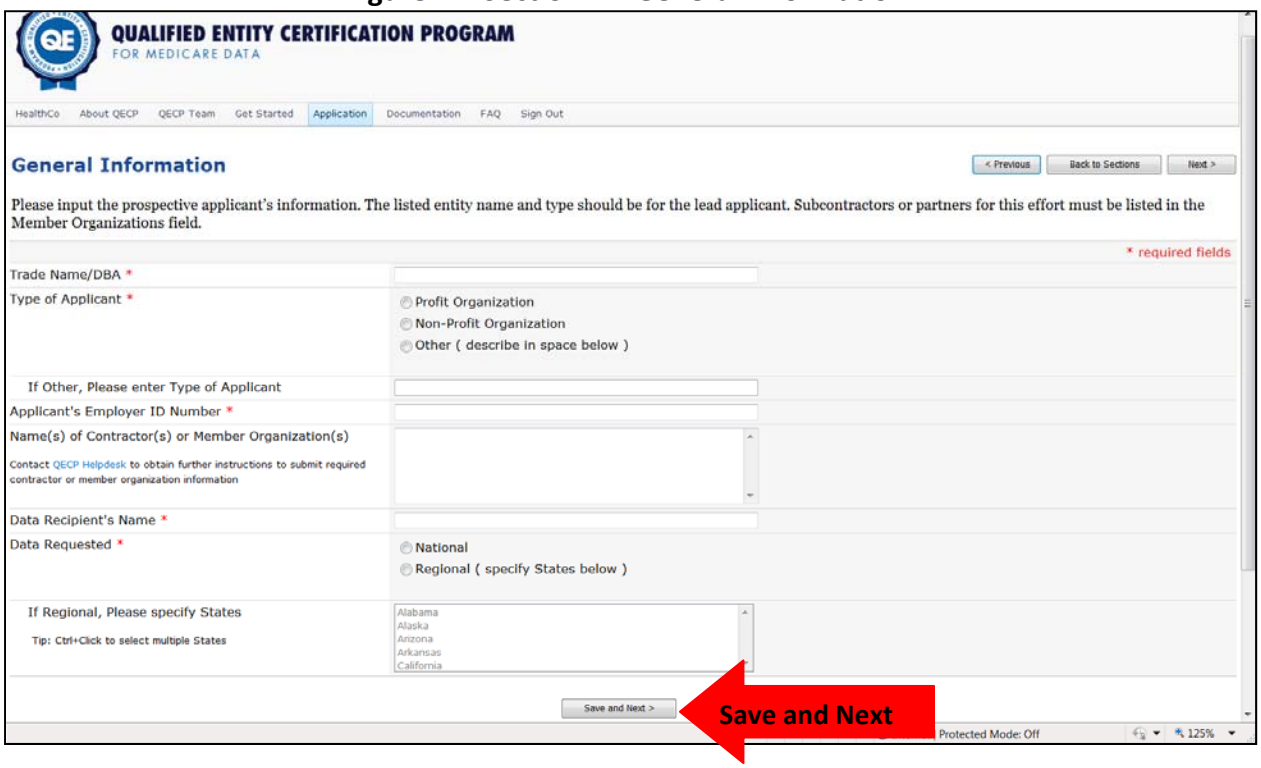
6. COMPLETING APPLICATION SECTION 1 – GENERAL INFORMATION

Section 1 of the application asks for general information (Figure 22). Please input the applicant's information. The listed entity name and type should be for the lead applicant. Subcontractors or partners for this effort must be listed in the Member Organizations field.

The information required includes:

1) *Trade Name/DBA*
2) *Type of Applicant*
    a. Select one from the list.
    b. If "other" is selected, please describe type in the field below.
3) *Applicant's Employer ID Number* – This is your Federal Employer Identification Number
4) *Name(s) of Contractor(s) or Member Organization(s)*
5) *Data Recipient's Name*
6) *Data Requested*
    a. Select **National** or **Regional.**
    b. Specify state(s) if Regional is selected. To select more than one state, hold **CTRL** and select all states for which you plan to request data.

Figure 22. Section 1 – General Information

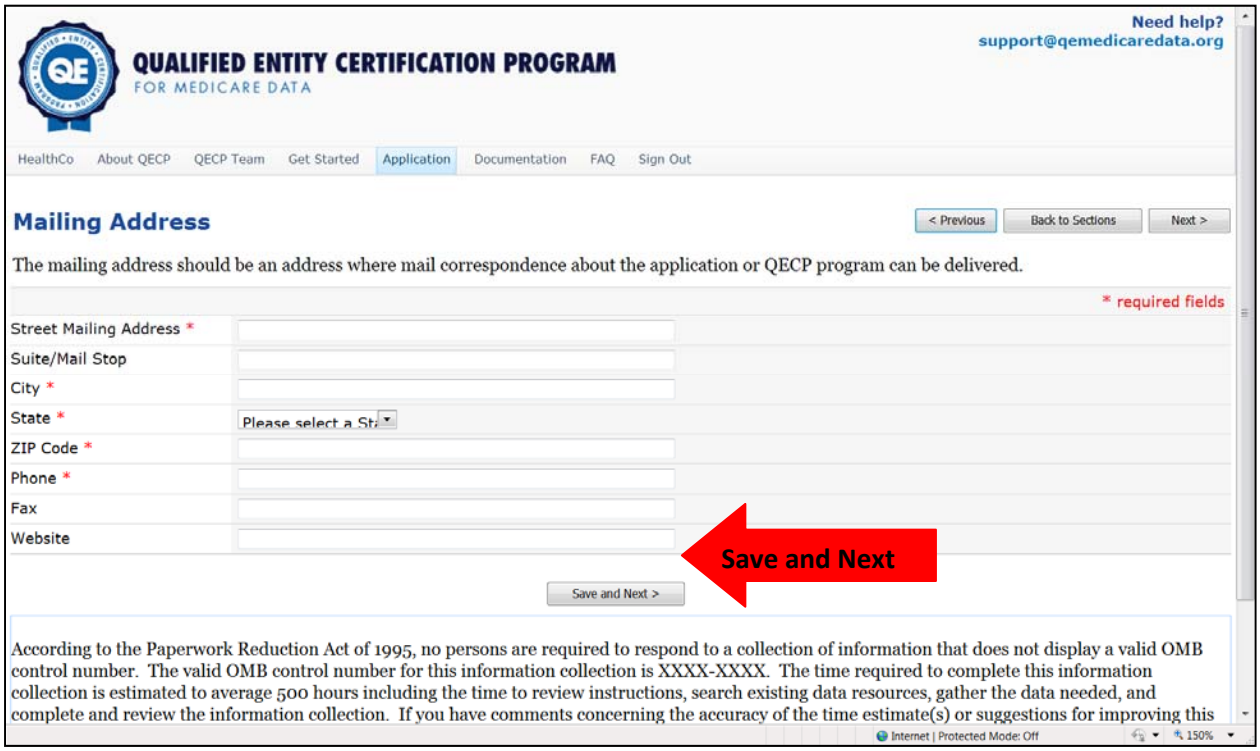


Click **Save and Next** to save your work before continuing to the next section. To move to another section without saving your work, click **Previous**, **Next**, or **Back to Sections** from the navigation tools in the top right corner.

7. COMPLETING APPLICATION SECTION 2 – MAILING ADDRESS

Section 2 of the application requests the mailing address where mail correspondence about the application or QECP program can be delivered (Figure 23).

Figure 23. Section 2 – Mailing Address



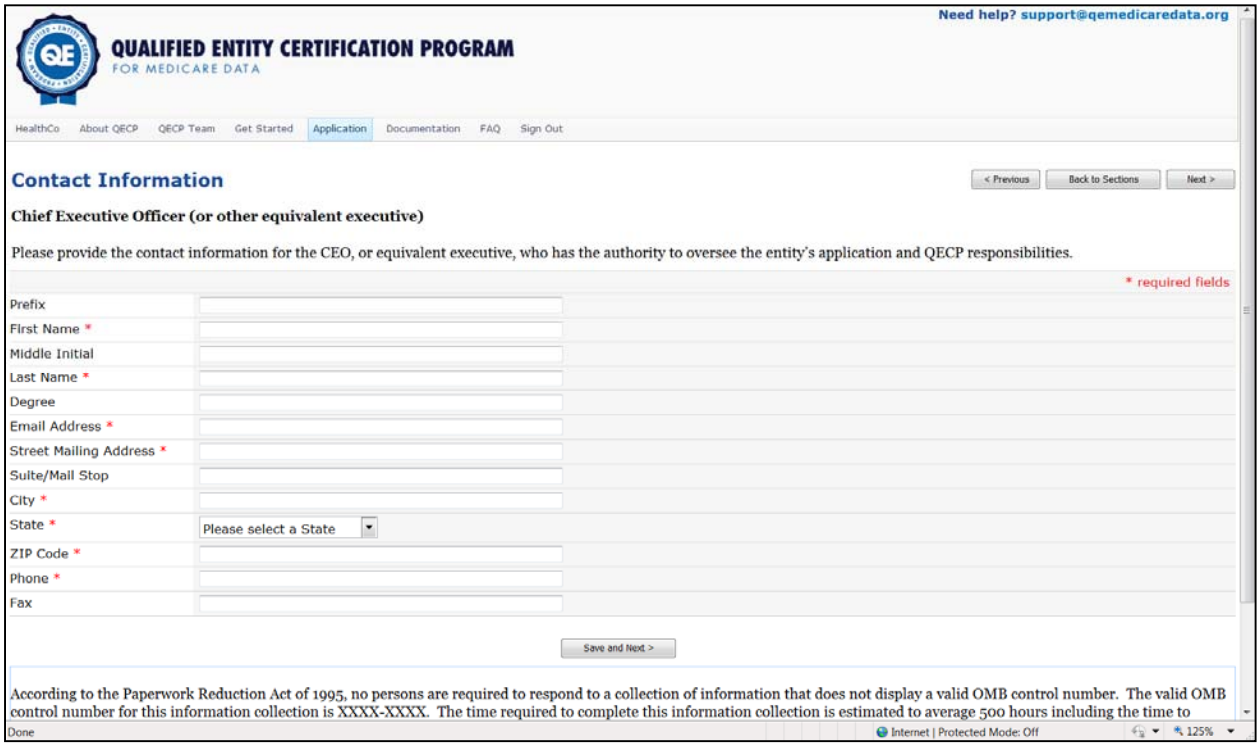
Click **Save and Next** to save your work before continuing to the next section. To move to another section without saving your work, click **Previous**, **Next**, or **Back to Sections** from the navigation tools in the top right corner.

8. COMPLETING APPLICATION SECTION 3 – CONTACT INFORMATION

Section 3 requires information for two contacts:

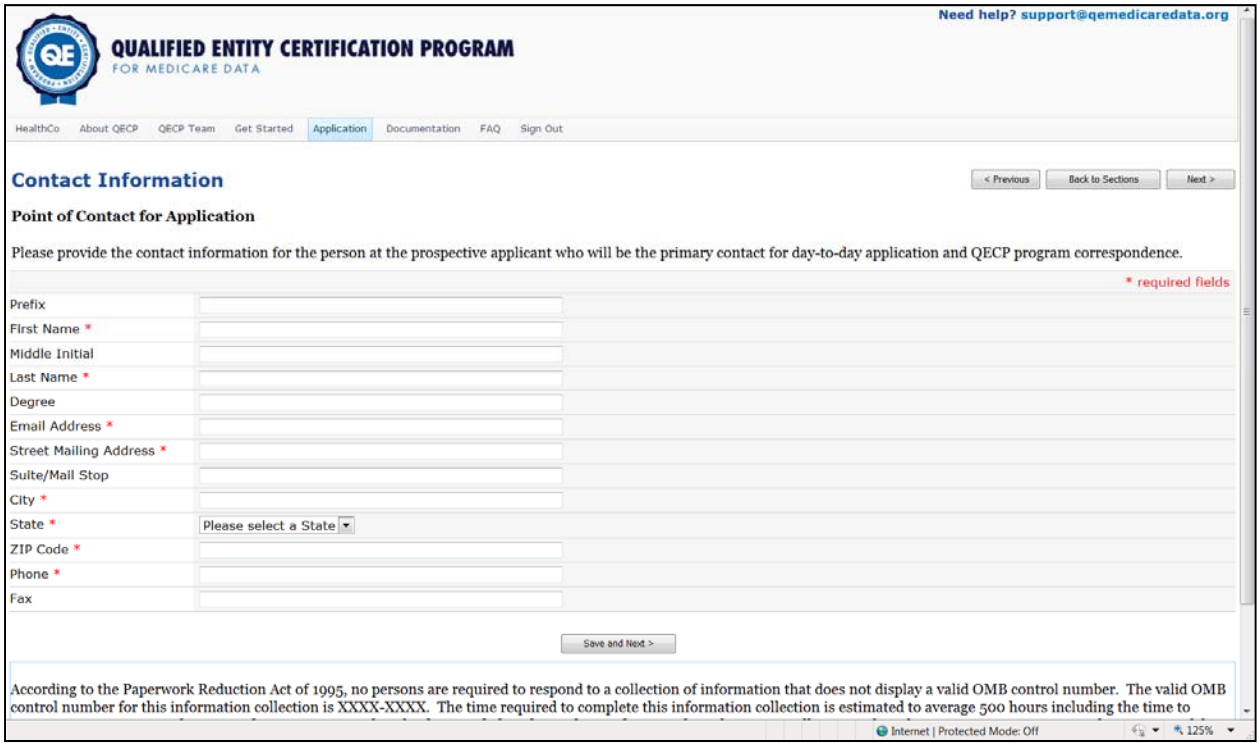
1) Your entity's chief executive officer (or other equivalent executive) (Figure 24)
2) Your entity's point of contact for the application (Figure 25)

Figure 24. Section 3 – Contact Information: Chief Executive Officer



The first contact (Figure 24) should have the authority to oversee the entity's application and QECP responsibilities if the entity is certified. The second contact (Figure 25) will be the person contacted during the application review if questions arise and will serve as the primary contact for day-to-day application and QECP program correspondence.

Figure 25. Section 3 – Contact Information: Point of Contact for Application



9. UNDERSTANDING SECTION 4 – STANDARDS

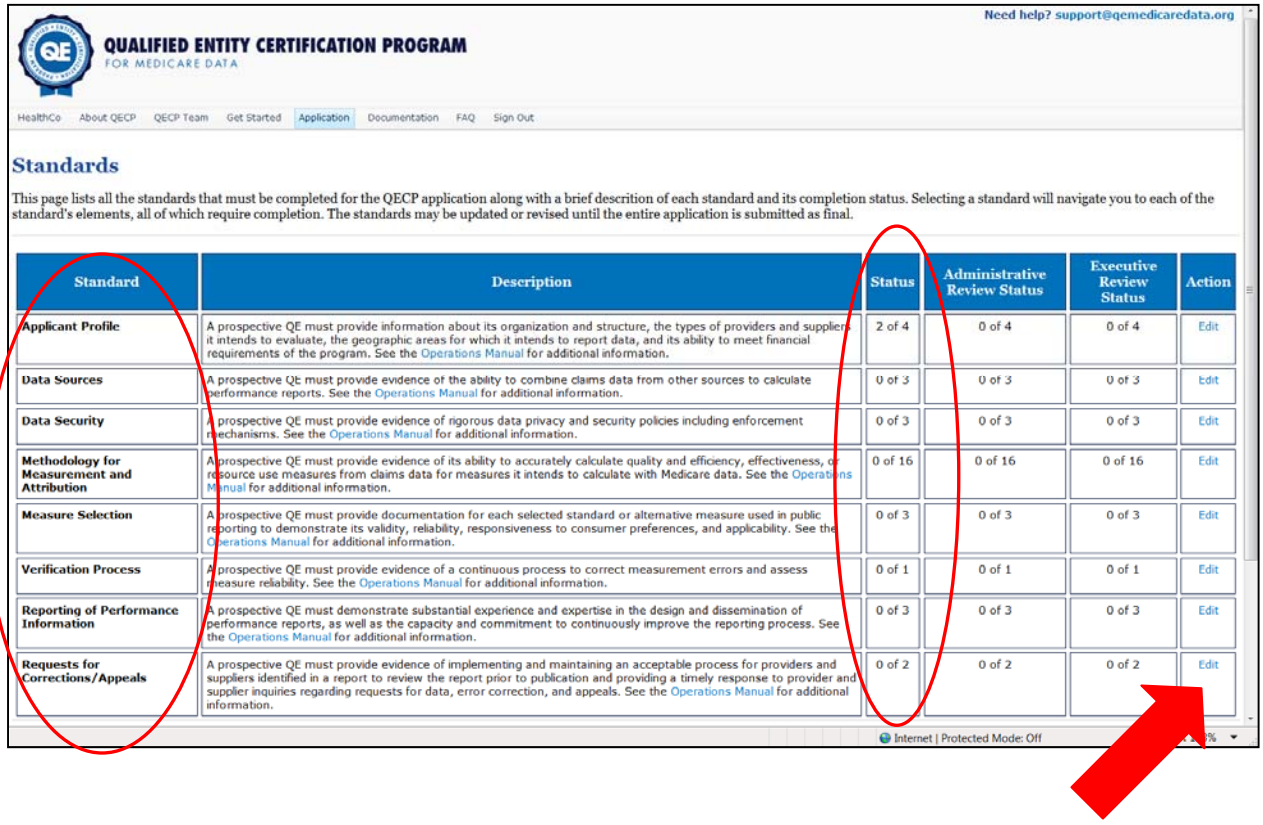
Section 4 lists all the standards (left-hand column) that must be completed for the QECP application, together with a brief description of each standard and its completion status. You can select the standards in any order, but all the standards must be completed. You may update or revise your entries under the standards until the time that the entire application is submitted as final.

Eight standards must be completed (Figure 26):

1) Applicant Profile
2) Data Sources
3) Data Security
4) Methodology for Measurement and Attribution
5) Measure Selection
6) Verification Process
7) Reporting of Performance Information
8) Requests for Corrections/Appeals

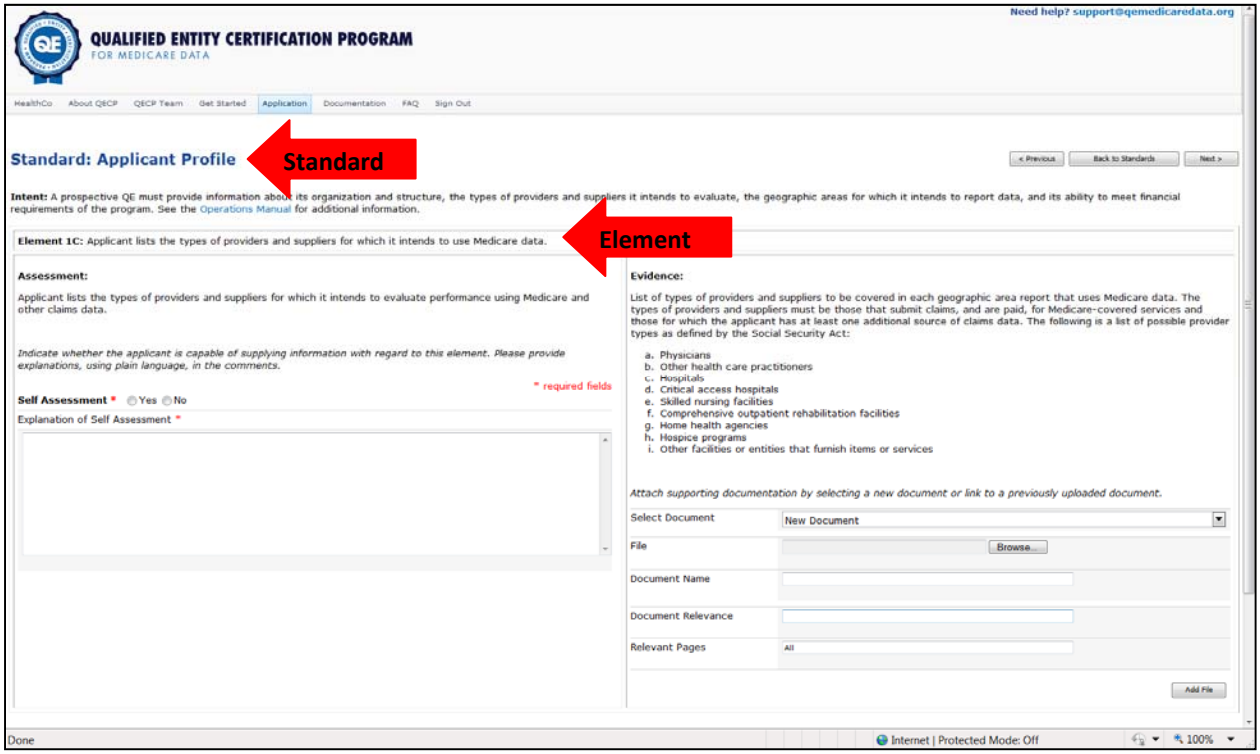
Each of the standards contains one or more components called ***elements***. The number of elements associated with a standard may be seen under the **Status** column, which also tracks your progress within each standard. To begin entering information for a standard, click **Edit** under the **Action** column on the right-hand side.

Figure 26. Section 4 – Standards



Once you select a standard, a new page will appear (Figure 27). The standard is listed in the top left corner with a description below the title of the standard. The element is then identified below the description of the standard.

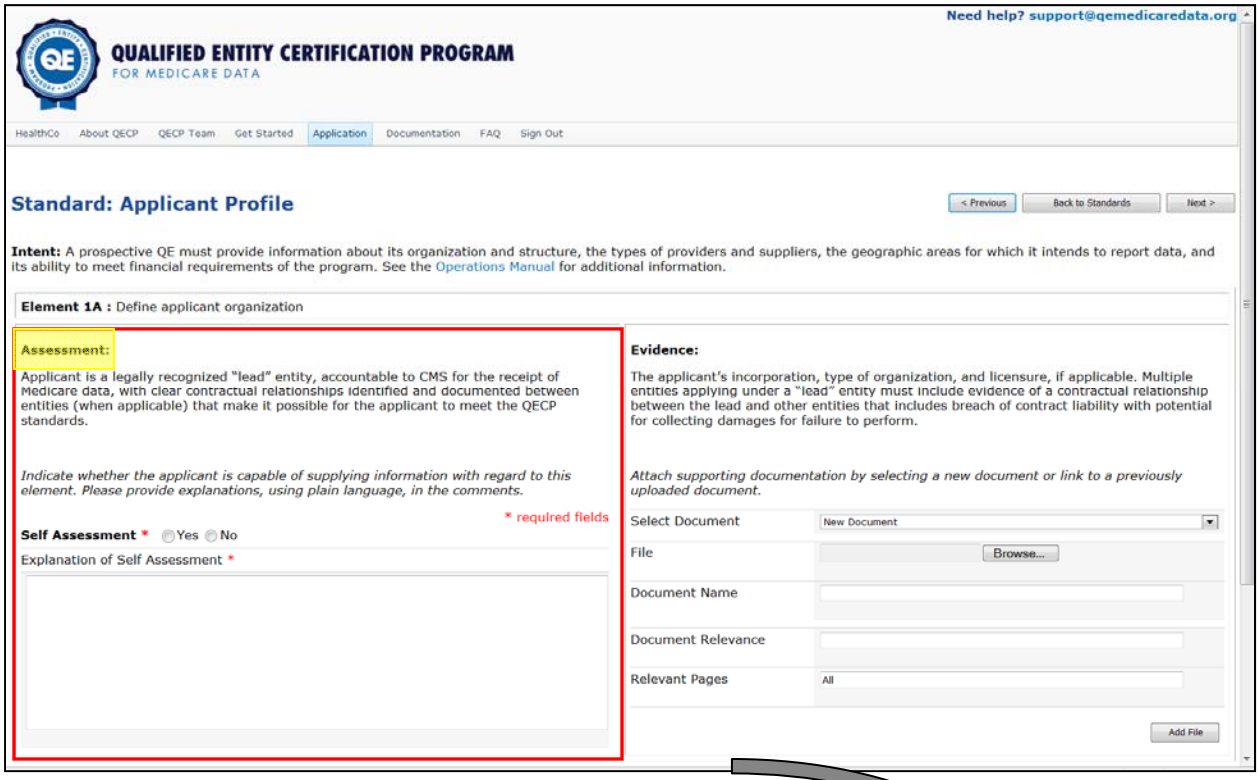
Figure 27. Standard/Element Layout



Each standard is comprised of one or more elements. Every element has two parts:

1) ***Assessment*** (Figures 28 and 29)
2) ***Evidence*** (Figures 30 and 31)

Figure 28. Part I: Assessment



For the ***Assessment*** (Figure 29):

1) Read the assessment statement.
2) Select **Yes** or **No.**
3) Provide an explanation of your self-assessment.

Figure 29. Assessment

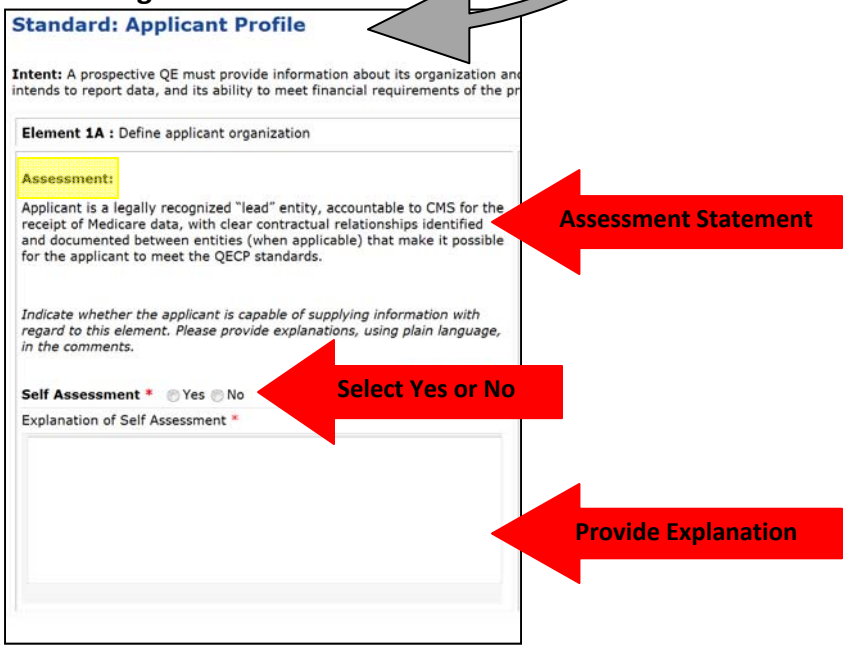
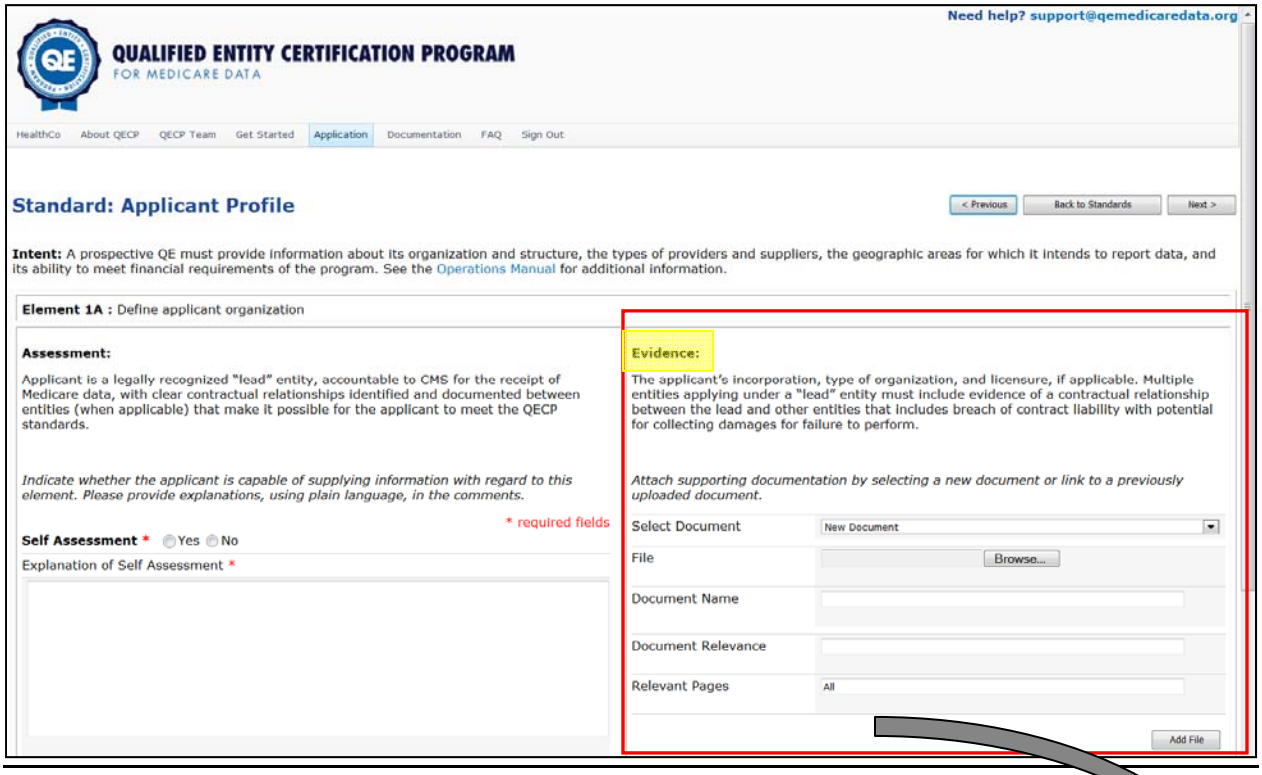


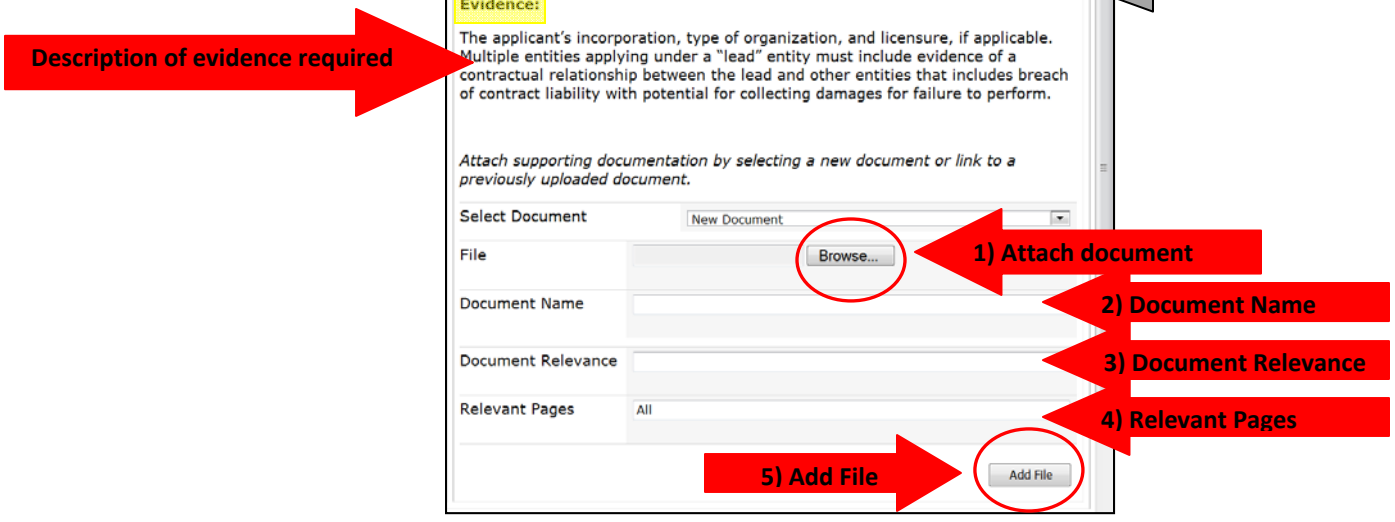
Figure 30. Evidence



For the ***Evidence*** (Figures 30 and 31)

1) Attach supporting documentation by selecting **Browse** next to the file field.
2) Type in the document name.
3) Explain why the document is relevant to the element.
4) Type in relevant pages of the document.
5) Click **Add File.**

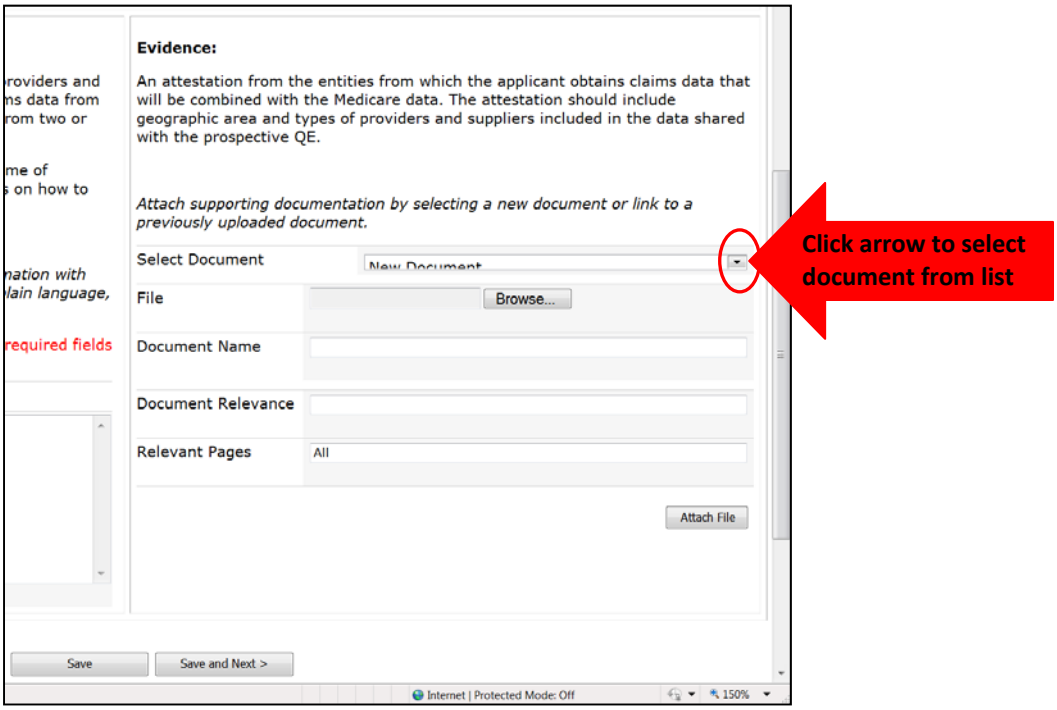
Figure 31. Attaching Documentation



Once a document has been uploaded according to steps 1 through 5 above, the document is stored in a database. You may reference the same document for multiple standards and/or elements.

To reference a previously uploaded document, select the correct document name from the drop-down list next to the **Select Document** field (Figure 32). All documents that have been uploaded will appear in this list. Then enter the document name, document relevance, and relevant pages.

Figure 32. Referencing Previously Uploaded Documentation



Click **Save and Next** to save your work and move to the next section, or click **Save** to save your work without continuing to the next section.

The following sections provide specific instructions related to each of the eight standards. The process is the same for each standard; however, the information and documentation required varies.

10. COMPLETING SECTION 4 – STANDARD 1

Standard 1 – Applicant Profile requires you to provide information about its organization and structure, the types of providers and suppliers it intends to evaluate, the geographic areas for which it intends to report data, and its ability to meet financial requirements of the program.

Standard 1 has four elements:

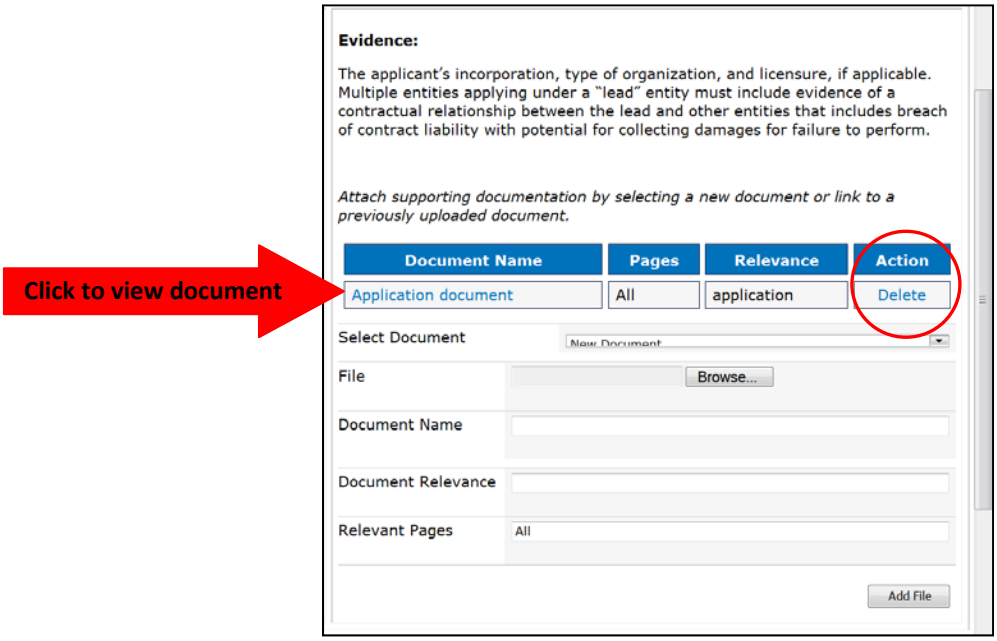
Element 1A: Define applicant organization
Element 1B: Identify the geographic areas that applicant's reports will cover
Element 1C: Identify the types of providers or suppliers whose performance applicant intends to assess using Medicare data
Element 1D: Show ability to cover the costs of performing the required functions of a qualified entity

To satisfy the requirements for Standard 1, the assessment and evidence sections must be completed for all four elements. There are four separate pages that can be accessed by clicking the navigation buttons (**Previous**, **Back to Standards**, **Next**) in the top right corner. The following process must be completed for Element 1A, Element 1B, Element 1C and Element 1D:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No.**
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document.**
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open.**
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where relevant sections can be found.
    f. Click **Add File.**
    g. Click **Save and Next** to move to the next section.

If you need to remove an uploaded file, you can do so by clicking **Delete** in the **Action** column on the right (Figure 33). To view the contents of the document before deleting, click the document name.

Figure 33. Deleting Documentation



11. COMPLETING SECTION 4 – STANDARD 2

Standard 2 – Data Sources requires you to provide evidence of your ability to combine claims data from other sources to calculate performance reports.

Standard 2 has two elements:

Element 2A: Obtain claims data from at least one other payer sources to combine with Medicare Parts A and B claims data and Part D drug event data

Element 2B: Accurately combine Medicare claims data from other payer sources

To satisfy the requirements for Standard 2, the assessment and evidence sections must be completed for both elements. There are two separate pages that can be accessed by clicking the navigation buttons (**Previous**, **Back to Standards**, **Next**) in the top right corner. The following process must be completed for Element 2A and Element 2B:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No**.
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document.**
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open**.
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where the relevant sections can be found.
    f. Click **Add File**.
    g. Click **Save and Next** to move to the next section.

12. COMPLETING SECTION 4 – STANDARD 3

Standard 3 – Data Security requires you to provide evidence of rigorous data privacy and security policies, including enforcement mechanisms.

Standard 3 has three elements:

Element 3A: Administrative (show ability to comply with Federal data security and privacy requirements, and document a process to follow those protocols)
Element 3B: Technical (identify system users and prequalification for access to data)
Element 3C: Physical (identify processes and systems in place to physically protect the IT infrastructure)

To satisfy the requirements for Standard 3, the assessment and evidence sections must be completed for all three elements. There are three separate pages that can be accessed by clicking the navigation buttons (**Previous**, **Back to Standards**, **Next**) in the top right corner. The following process must be completed for Element 3A, Element 3B, and Element 3C:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No**.
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document**.
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open**.
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where the relevant sections can be found.
    f. Click **Add File**.
    g. Click **Save and Next** to move to the next section.

13. COMPLETING SECTION 4 – STANDARD 4

Standard 4 – Methodology for Measurement and Attribution requires you to provide evidence of its ability to accurately calculate quality and efficiency, effectiveness, or resource use measures from claims data for measures it intends to calculate with Medicare data.

Standard 8 has five elements:

Element 4A: Follow measure specifications
Element 4B: Use a defined and transparent method for attribution of patients and episodes
Element 4C: Set and follow requirements to establish statistical validity of measure results for quality measures
Element 4D: Set and follow requirements to establish statistical validity of measure results for efficiency, effectiveness, and resource use measures
Element 4E: Use appropriate methods to employ risk adjustment
Element 4F: Use appropriate methods to handle outliers
Element 4G: Use comparison groups when evaluating providers or suppliers compared to each other
Element 4H: Use benchmarks when evaluating providers

To satisfy the requirements for Standard 4, the assessment and evidence sections must be completed for all eight elements. There are eight separate pages that can be accessed by clicking the navigation buttons (**Previous**, **Back to Standards**, **Next**) in the top right corner. The following process must be completed for Element 4A, Element 4B, Element 4C, Element 4D, Element 4E, Element 4F, and Element 4G:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No**.
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document.**
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open.**
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where the relevant sections can be found.
    f. Click **Add File**.
    g. Click **Save and Next** to move to the next section.

14. COMPLETING SECTION 4 – STANDARD 5

Standard 5 – Measure Selection requires you to provide documentation for each selected standard or alternative measure used in public reporting to demonstrate its validity, reliability, responsiveness to consumer preferences, and applicability.

Standard 5 has two elements:

Element 5A: Use standard measures
Element 5B: Use approved alternative measures

To satisfy the requirements for Standard 5, the assessment and evidence sections must be completed for both elements. There are two separate pages that can be accessed by clicking the navigation buttons (**Previous**, **Back to Standards**, **Next**) in the top right corner. The following process must be completed for Element 5A and Element 5B:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No**.
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document**.
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open**.
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where the relevant sections can be found.
    f. Click **Add File**.
    g. Click **Save and Next** to move to the next section.

15. COMPLETING SECTION 4 – STANDARD 6

Standard 6 – Verification Process requires you to provide evidence of a continuous process to correct measurement errors and assess measure reliability.

Standard 6 has one element:

Element 6A: Systematically evaluate accuracy of the measurement process and correct errors

To satisfy the requirements for Standard 6, the assessment and evidence sections must be completed for Element 6A:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No.**
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document**.
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open**.
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where the relevant sections can be found.
    f. Click **Add File**.
    g. Click **Save and Next** to move to the next section.

16. COMPLETING SECTION 4 – STANDARD 7

Standard 7 – Reporting of Performance Information requires you to demonstrate substantial experience and expertise in the design and dissemination of performance reports, as well as the capacity and commitment to continuously improve reporting process.

Standard 7 has two elements:

Element 7A: Design reporting for providers, suppliers and the public
Element 7B: Improve reporting

To satisfy the requirements for Standard 7, the assessment and evidence sections must be completed for both elements. There are two separate pages that can be accessed by clicking the navigation buttons (**Previous**, **Back to Standards**, **Next**) in the top right corner. The following process must be completed for Element 7A and Element 7B:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No.**
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document.**
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open**.
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where the relevant sections can be found.
    f. Click **Add File**.
    g. Click **Save and Next** to move to the next section.

17. COMPLETING SECTION 4 – STANDARD 8

Standard 8 – Requests for Corrections/Appeals requires you to provide evidence of implementing and maintaining an acceptable process for providers and suppliers identified in a report to review the report prior to publication and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

Standard 8 has two elements:

Element 8A: Use corrections process
Element 8B: Use secure transmission of beneficiary data

To satisfy the requirements for Standard 8, the assessment and evidence sections must be completed for both elements. There are two separate pages that can be accessed by clicking the navigation buttons (**Previous**, **Back to Standards**, **Next**) in the top right corner. The following process must be completed for Element 8A, and Element 8B:

1) **Assessment**:
    a. Read the self-assessment statement.
    b. Select **Yes** or **No.**
    c. Provide an explanation for your selection.
2) **Evidence**:
    a. Read the evidence required.
    b. Attach supporting documentation:
        i. Select **New Document**.
        ii. Click **Browse** to choose a file from your computer.
        iii. Select the correct document.
        iv. Click **Open**.
    c. Type in the document name.
    d. Explain why the document is relevant to this element.
    e. Provide specific page numbers where the relevant sections can be found.
    f. Click **Add File**.
    g. Click **Save and Next** to move to the next section.

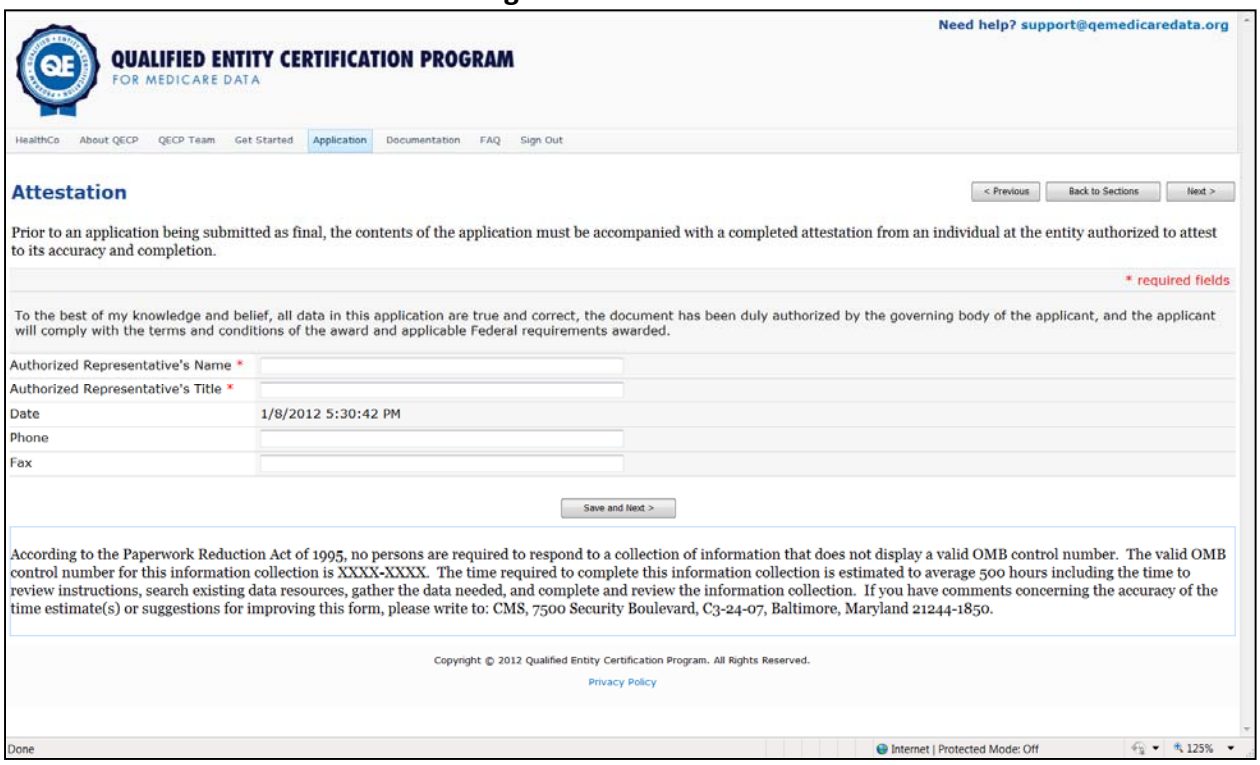
18. COMPLETING APPLICATION SECTION 5 – ATTESTATION

Prior to an application being submitted as final, the contents of the application must be accompanied by a completed attestation (below) from an individual at the entity who is authorized to attest to its accuracy and completion.

You must provide:

1) Authorized representative's name
2) Authorized representative's title
3) Phone
4) Fax (optional)

Figure 34. Attestation

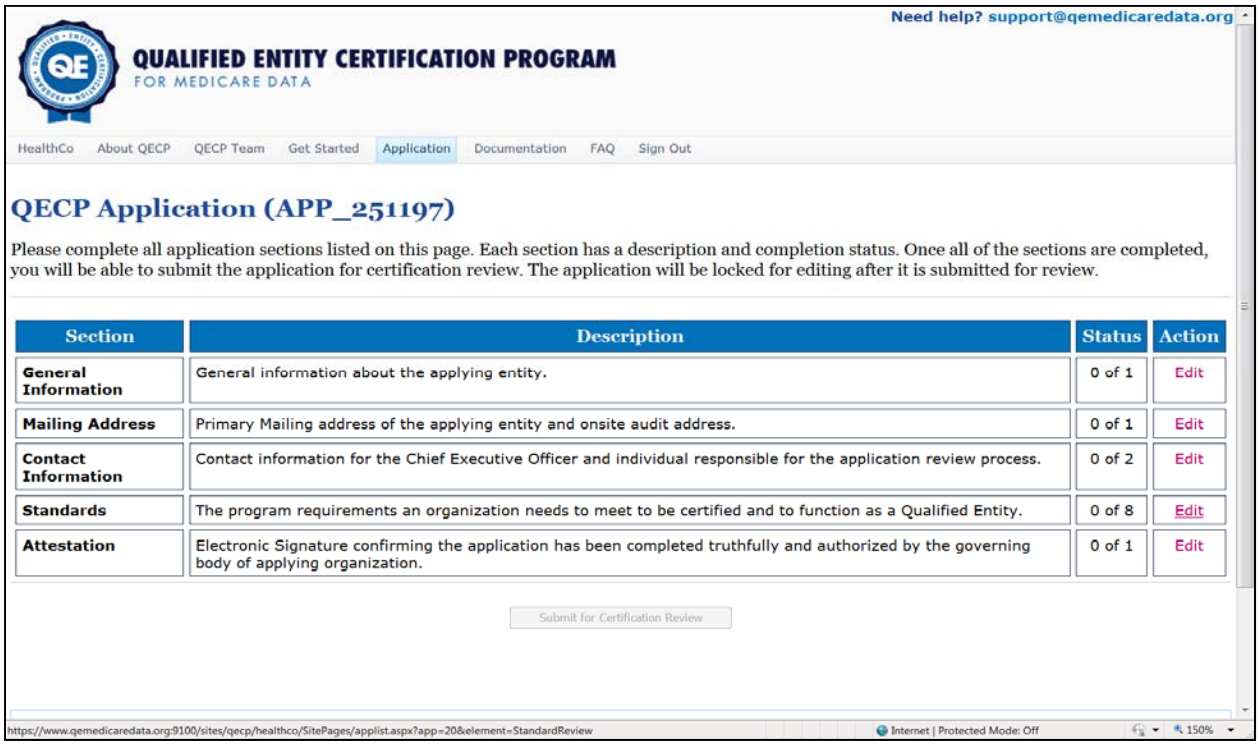


Once the required fields are completed, click **Save and Next** to submit the attestation.

19. SUBMITTING THE APPLICATION

Once you have completed all five sections, including the attestation and the uploading of the required documentation, click **Submit for Certification Review** (Figure 35). Once you do this, the application will be locked and no further changes can be made.

Figure 35. Application Submission



After the application is submitted, a completion screen will appear (Figure 36). At that time, your application will be validated for completeness, and if found complete, its QECP review will commence.

Figure 36. Application Submitted

If, after submitting your application you discover errors or that the documentation is incomplete, please contact technical support at support@qemedicaredata.org to resolve the issue.

2012 OPERATIONS MANUAL

APPENDIX E. GLOSSARY

APPENDIX E: GLOSSARY

A

Additional User – An individual who has completed a registration form via the QECP Portal and has been verified by the entity's administrative user to access the restricted pages of the QECP Portal (including the entity's QE application).

Administrative Reviewer – The individual who conducts the first review of an entity's application and reviews its submitted evidence against the program's minimum requirements (the standards and elements).

Administrative User – The first individual from an entity to complete a registration form via the QECP Portal. This individual will be prompted by QECP Portal administrators to verify the access of additional users from the entity to the restricted pages of the QECP Portal (including the entity's QE application).

Alternative Measure – A non-standard measure, calculated in full or in part from claims data from other sources and standardized extracts of Medicare Parts A and B claims and Part D prescription drug event (PDE) data, that has been deemed to be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use than existing claims-based standard measures.

Applicant – An entity whose application for QE certification has been validated by the QECP team and is either in the process of submitting additional evidence/supporting documentation (at the request of the review coordinator) or waiting for a certification decision.

Application – All information submitted by entities during the application process including general information, contact information, mailing address, self-assessment check marks, text submitted in comment boxes, evidence/supporting documentation, data security POA&M (if required), and signature.

Assessment – The component(s) of an element that the entity must demonstrate to meet the minimum requirements for that element in order to receive approval for the element. Several assessments may be required for a single element; assessments reflect an entity's degree of compliance with an element.

B

Beneficiary Identifiable Data – Any data that contains the beneficiary's name, Medicare Health Insurance Claim Number (HICN), or any other direct identifying factors, including, but not limited to, postal address or telephone number.

Beneficiary Summary File – Demographic and enrollment information for Medicare beneficiaries consisting of state and county of residence codes, zip code, date of birth, date of death, sex, race, age, monthly entitlement indicators (A/B/C/D), reasons for entitlement, state buy-in indicators, and monthly managed care indicators (yes/no). From 2006 forward, it also includes variables specific to enrollment in the Medicare Part D prescription drug program. These variables include a derived race/ethnicity code, an indicator for Other Credible Drug Coverage, and monthly indicators for Medicare Advantage Prescription Drug (MA-PD) and stand-alone Prescription Drug Plan (PDP) enrollment, Low Income Subsidy (LIS) enrollment, Retiree Drug Subsidy, and state-reported dual eligibility status.

C

Chronic Condition Data Warehouse (CCW) – A research database designed to make Medicare, Medicaid, and Part D prescription drug event (PDE) data more readily available to support research designed to improve the quality of care and reduce costs and utilization.

Claim – An itemized billing statement from a provider or supplier that, except in the context of Part D prescription drug event data, requests payment for a list of services and supplies that were furnished to a Medicare beneficiary in the Medicare fee-for-service context, or to a participant in other insurance or entitlement program contexts. In the Medicare program, claims files are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers and suppliers) claim type as well as Medicare Part D prescription drug event (PDE) data.

Claims Data from Other Sources – Provider- or supplier-identifiable claims data that an applicant or qualified entity has full data usage right to due to its own operations or disclosures from providers, suppliers, private payers, multi-payer databases, or other sources.

Clinical Data – Registry data, chart-abstracted data, laboratory results, electronic health record information, or other information relating to the care or services furnished to patients that is not included in administrative claims data, but is available in electronic form.

D

Data Use Agreement (DUA) – Contractual agreement between the Centers for Medicare & Medicaid Services (CMS) and an external entity, which must be established prior to disclosing data and which requires the entity to comply with the requirements of the Federal Privacy Act, the HIPAA Privacy Rule, and CMS data release policies.

E

Element – The component of a standard that is scored/reviewed and provides details about performance expectations. Each element within a standard is evaluated to determine the degree to which the entity has met the requirements of the standard.

Encrypted Data – Any data that does not contain the beneficiary's name or any other direct identifying factors, but does include a unique CMS-assigned beneficiary identifier that allows for the linking of claims without divulging any direct identifier of the beneficiary.

Entity – Any legally recognized organization (public or private) interested in applying for certification to become a qualified entity (QE).

Evidence – An item that is submitted to demonstrate compliance with an element. The evidence allows reviewers to evaluate whether the entity meets the assessment.

Executive Reviewer – The individual who conducts the final application review, which is an independent review of the application, and incorporates and considers the administrative review findings.

F

Final Rule – 42 CFR, Part 401, Subpart G, titled "Medicare Program; Availability of Medicare Data for Performance Measurement – Final Rule," published in the *Federal Register*, Vol. 76, No. 235, December 7, 2011, and available at: http://www.gpo.gov/fdsys/pkg/FR-2011-12-07/pdf/2011-31232.pdf.

G

H

I

Intent – A brief description of the purpose of an application standard.

J

K

L

Lead Entity – An entity that chooses to contract with one or more outside entities to meet the minimum requirements of the QECP and function as a QE. The lead entity is responsible for completing the application, including the submission of contractual agreements with all outside entities. In addition, the lead entity is responsible for ensuring that outside entities comply with all program requirements related to the Data Use Agreements (DUA), evaluation, monitoring, and oversight.

M

Medicare Part A Claims Data - Fee-for-service claims from institutional health care providers that include the following claim types:

- *Inpatient* – from inpatient hospital providers for reimbursement of facility costs (includes variables such as diagnosis and procedure codes, Diagnosis Related Group, dates of service, reimbursement amount, and provider number);
- *Skilled Nursing Facility* – from skilled nursing facilities (includes variables such as diagnosis and procedure codes, dates of service, reimbursement amount, and provider number);
- *Outpatient* – from outpatient providers such as hospital outpatient departments, rural health clinics, renal dialysis facilities, outpatient rehabilitation facilities, and community mental health centers (includes variables such as diagnosis and procedure codes, CMS Common Procedure Coding System codes, dates of service, reimbursement amount, provider number, and revenue center codes);
- Hospice – from hospice providers (includes level of hospice care received [e.g., routine home care, inpatient respite care], terminal diagnosis code, dates of service, reimbursement amount, and provider number); and
- *Home Health* – from home health care providers (includes variables such as number of visits, type of visit, diagnosis code, dates of visits, reimbursement amount, and provider number).

Medicare Part B Claims Data – Fee-for-service claims from non-institutional health care providers that include the following claim types:

- *Carrier* – from non-institutional providers such as physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, ambulance providers, and free-standing ambulatory surgical centers (includes variables such as diagnosis and procedure codes, CMS Common Procedure Coding System codes, dates of service, reimbursement amount, and provider number); and
- *Durable Medical Equipment Regional Carrier* – from durable medical equipment suppliers (includes diagnosis codes, CMS Common Procedure Coding System codes, dates of service, reimbursement amount, and provider number).

Medicare Part D Prescription Drug Event (PDE) Data – Summary extracts of CMS-defined standard prescription fills (not individual drug claim transactions) submitted by Medicare prescription drug plan sponsors to CMS. The PDE data include such variables as prescriber identifier, quantity dispensed, days supply, fill number, gross drug cost below/above out-of-pocket threshold, patient pay amount, and other transactional information.

Minimum Requirements – The collection of standards and elements that an entity must meet in order to become certified as a qualified entity. These requirements are derived directly from the Final Rule (42 CFR, Part 401, Subpart G).

N

O

Operations Manual – A comprehensive document that describes QECP operations and policies, including all CMS requirements that prospective applicants and certified QEs must meet, as well as step-by-step instructions on the application process. The Operations Manual is revised and re-released in its entirety annually.

Operations Manual Update – A supplemental stand-alone document that serves as an addendum to the annually released Operations Manual. The update serves to inform all interested parties about QECP policy and procedural changes since the previous annual release of the Operations Manual.

P

Plan of Action and Milestones (POA&M) – A tool that identifies tasks that need to be accomplished. It details the resources required to accomplish the elements of the plan, any milestones to meet the task, and scheduled completion dates for the milestones. The purpose of the POA&M is to assist agencies in identifying, assessing, prioritizing, and monitoring the progress of corrective efforts for security weaknesses found in programs and systems.

Program Coordinator – The individual who is the entity's primary point of contact throughout the QECP process and who is responsible for validating the completeness of an application, assigning the applicant to their review team, assisting the applicant throughout their QECP participation, and facilitating contact between the applicant and the QECP team.

Prospective Applicant – An entity interested in applying for QE certification, but which has not yet finalized and submitted a complete application.

Providers of Services (referred to as Providers) – Those individuals whose performance will be calculated and publicly reported by QEs. As defined in 42 CFR § 400.202, "providers" include the following: hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, or hospices that have in effect an agreement to participate in Medicare, or clinics, rehabilitation agencies, or public health agencies that have in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or community mental health centers that have in effect a similar agreement but only to furnish partial hospitalization services.

Q

Qualified Entity (QE) – A single public or private entity, or a lead entity and its contractors, or, if the applicant is a collaborative, any member organization of the collaborative, that (1) is

qualified, as determined by the Secretary, to use claims data to evaluate the performance of providers and suppliers on measures of quality, efficiency, effectiveness, and resource use, and (2) agrees to meet regulatory requirements in 42 CFR §§ 401.705–401.721.

Qualified Entity Certification Program for Medicare Data (QECP) –The product of 42 CFR, Part 401, Subpart G, which was developed so that interested entities that successfully meet the criteria outlined in the Final Rule may become certified as qualified entities (QEs), and maintain their QE status.

QECP Portal – An online tool that supports the submission, review, and approval of applications from entities. It also facilitates ongoing technical support throughout the application process.

R

Re-apply – What a qualified entity in good standing must do at least six months before the end of their three-year certification approval period in order to continue performing the tasks of a QE. As part of a renewal application (or re-application), QEs must submit documentation of any changes to what was included in its previously-approved application.

Registration Form – The form that must be completed by an individual within an entity to obtain a user ID and password and gain access to the restricted pages of the QECP Portal, including the QE application.

Review – The application review process as a whole, from the time the application is first submitted, through the approval or denial of the applicant to be certified as a qualified entity.

Review Coordinator – The individual who is the applicant's primary point of contact during the application review process and who is responsible for facilitating contact between the applicant and the review team.

Review Team – Inclusive of the review coordinator, administrative reviewer, and executive reviewer. All members of the review team must meet specific education and experience qualifications.

S

Self-assess – The independent decision of entities regarding their ability to meet or not meet the elements described in the QE application form. During the application process, while submitting supporting documentation for each element, entities must answer "yes" or "no" in the self-assessment field. If they answer "no," they must submit an explanation in the comment box.

Standard – An area for review that defines the program requirements at the highest level. It includes intent, program elements, assessment, and evidence.

Standard Measure – A measure that can be calculated in full or in part from claims data from other sources and the standardized extracts of Medicare Parts A and B claims and Part D prescription drug event (PDE) data. The measure must fall into one of the following categories: measure is endorsed (or time-limited endorsed) by the entity with a contract under Section 1890(a) of the Social Security Act (currently the National Quality Forum); measure is currently being used in a CMS program that includes quality measurement; or measure was developed pursuant to Section 931 of the Public Health Service Act.

Standardized Data Extract – Medicare Parts A and B claims data and Part D drug event state-specific data representing 100 percent of the claims in the Chronic Condition Warehouse (CCW) for Medicare beneficiaries in a specific geographic area (nation, state, county, MSA, etc.) during a specific time period. These data will be provided to qualified entities after approval of the DUA and receipt of payment.

Suppliers – Those whose performance will be calculated and publicly reported by QEs. As defined in 42 CFR § 400.202, "suppliers" are physicians or other practitioners, or entities other than providers, that furnish health care services under Medicare.

T

U

V

Validation – The first step taken by the QECP team when reviewing an application for QE certification that ensures all self-assessments are complete, all elements have evidence attached, and contact information is complete as submitted. If an application is considered "validated," the entity is considered an "applicant," and an administrative and executive reviewer are assigned to review the content of the application. If an application does not pass validation, a program coordinator will contact the entity for additional information or evidence.

W

X

Y

Z

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

QUALIFIED ENTITY CERTIFICATION PROGRAM

FOR MEDICARE DATA