2022 PROGRAM GUIDE

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES

QUALIFIED ENTITY CERTIFICATION PROGRAM

FOR MEDICARE DATA

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OVERVIEW AND BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is providing this Program Guide to walk entities through the requirements and application process of the Qualified Entity Certification Program (QECP). The guide includes the CMS requirements that entities must meet to become certified as a qualified entity (QE) or quasi QE, instructions for the application process, and an explanation of how to maintain certification.

This section provides an overview and background of the QECP. Sections 1 through 3 present the instructions for the program's phased application process. Section 4 provides ongoing program administration (OPA) requirements. Section 5 contains information about the reapplication process; and finally, Section 6 provides information about additional uses of QE Medicare data.

Appendix A is a glossary of terms used throughout this Program Guide; terms included appear in **bold** throughout the text. Appendix B lists resources including QECP team contact information, QE regulations, relevant websites, and locations of QECP webinars and tip sheets.

Implementing Regulations

The qualified entity regulations at 42 CFR Part 401, Subpart G establish the criteria that entities must satisfy to obtain QE and quasi QE certification, and set forth CMS' expectations for maintaining certification. In particular, the regulations provide requirements for entities in the following areas:

- Organizational structure and governance criteria, including necessary experience and expertise in the measures that entities intend to use for public reporting.
- Expertise in combining Medicare claims data with claims data from other sources, or in the case of quasi QEs, clinical data.
- Expertise in establishing rigorous data security and privacy programs.

While the Program Guide primarily describes the requirements for QEs, **qualified clinical data registries (QCDRs),** which may apply to become quasi QEs must meet the same requirements unless otherwise stated in this guide. The exceptions to the QECP requirements are Element 1.3 (Experience) and part of Element 1.4 (Claims Data) and, in certain cases, all elements associated with Phase 3. For more information on the requirements for quasi QEs, please see the User Guide for QCDRs. For more information on the difference between the certification processes for QEs and quasi-QEs, please see the FAQs. Organizations recognized by CMS as qualified registries (QRs) are not eligible to apply for the quasi QE program. However, QRs can apply to the QE program as long as they meet QECP program requirements.

Program Eligibility and Participation Requirements

To be eligible to participate in the program as a QE, an applicant (itself or through contracts with other entities) must:

1. Have access to sufficient claims data from other sources to combine with the **QE Medicare data**;
2. Have strong systems to ensure that the data are secure and protected; and
3. Have experience in a variety of tasks related to the calculation and reporting of performance measures, including:

a. combining claims data from different payers,
b. designing and sharing public reports,
c. working with **providers** and **suppliers** regarding requests for error correction, and
d. ensuring the privacy and security of data.

To participate in the QECP, entities must meet minimum requirements in each of these areas through a phased application and review process, described in this guide (see Sections 1–4).

The QECP is an open application program, which means that there are no application submission deadlines. There is also no charge to apply to become a QE or to maintain QE status. However, QEs are required to pay a fee for obtaining QE Medicare data.

Within 1 year of receiving QE Medicare data, each QE is required to release its first QE public report, and public reports are expected to be released annually thereafter.

Phased Minimum Requirements Review

To assess an organization's compliance with the program requirements, the QECP implements a three-phase process. Throughout the application process, each QE works closely with its QECP **Program Manager (PM)**.

A brief overview of the phases follows:

1. **Phase 1: Eligibility & Experience:** The QECP team examines an entity's organizational structure, its ability to successfully function as a QE, and its access to **other-payer claims data** (or **clinical data** for QCDRs).
2. **Phase 2: Data Security:** The QECP team examines the QE's compliance with the data security and privacy requirements of the program, as well as the corrections and appeals processes.
3. **Phase 3: Data Integration & Measure Calculations:** The QECP team examines the QE's compliance with the requirements related to the QE's measurement and reporting processes. Prior to submitting evidence for the Phase 3 review, the QE must integrate the QE Medicare data with its claims data from other sources and calculate provider performance measures.

Exhibits 1a and 1b show the phases of the application process for both QEs and quasi QEs. Exhibit 2 outlines the specific elements assessed during each phase. Detailed information on the evidence requirements for each phase is presented in Sections 1–3 of this Program Guide.

Exhibit 1a: QECP Phased Application Process for QEs

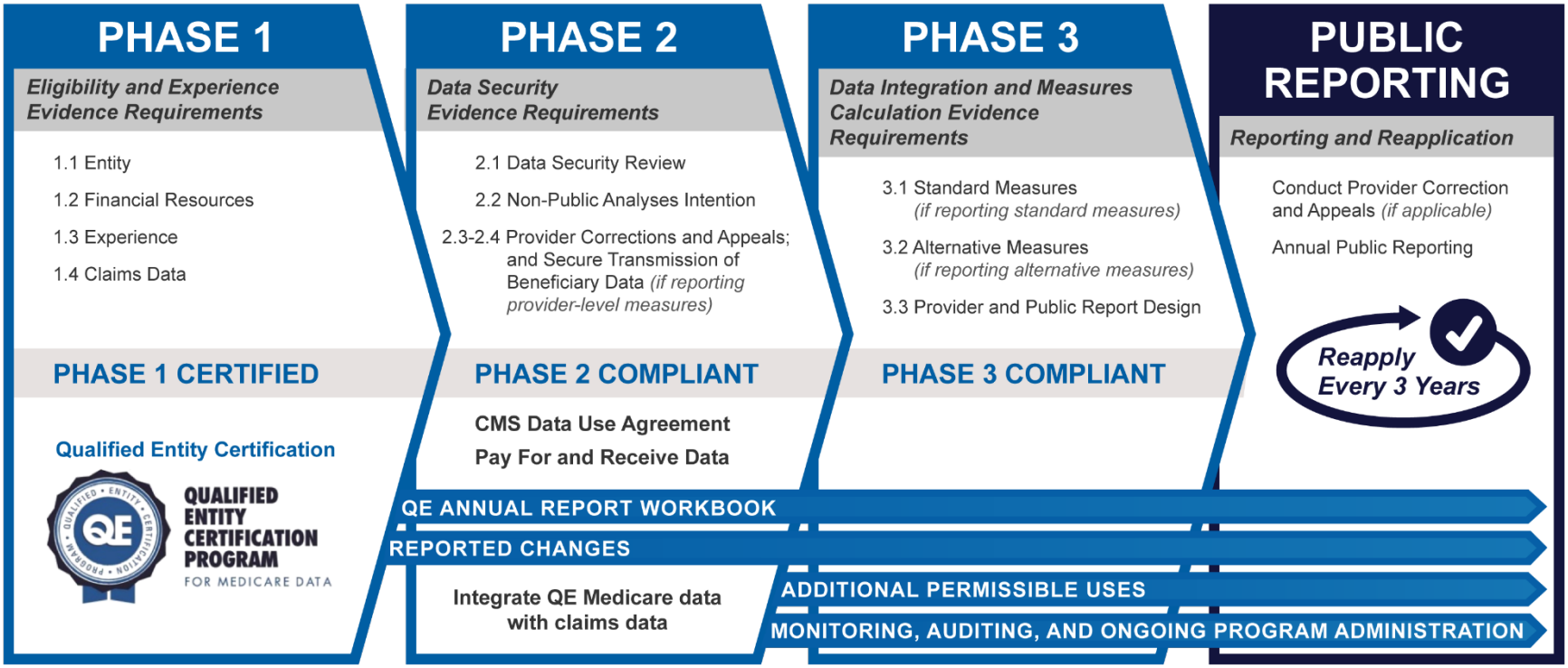

Exhibit 1b: QECP Phased Application Process for Quasi QEs

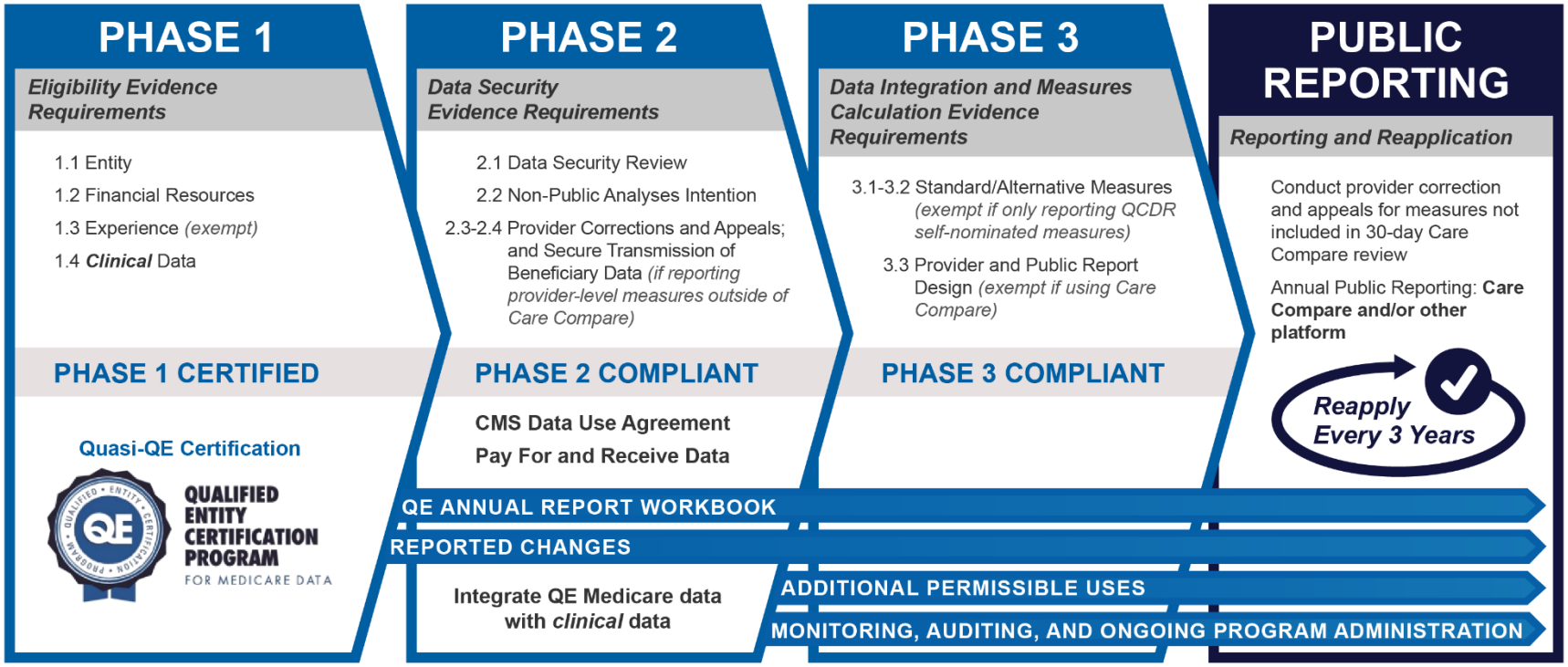

Exhibit 2: QECP Minimum Requirements Review: QECP Elements by Phase

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Getting Started

Prior to completing the application, an entity can indicate interest in the QECP by completing the publicly available QECP inquiry form (https://www.qemedicaredata.org/apex/Registration_Form). A PM will contact you within two business days of submitting your email inquiry or question. They will then schedule an Introductory Call to answer any questions the entity has about the program and gauge whether it is a good fit with its mission and objectives. If the entity intends to apply, the PM will schedule a Phase 1 Kick-Off Call and provide access to the QECP online application.

Application Process

The steps involved in the application review process are described below. These steps are repeated for the evaluation of each phase.

Application Review Steps (Repeated for Phases 1–3 and Reapplication)

1. The entity completes and submits its application, providing the evidence required. The application is completed online in the QECP Salesforce Application. For more information about how to use the web-based application, please review the QECP Application User`s guide.
2. The PM validates the application for completeness. If considered complete, the review begins. The entity is notified that the application has been accepted and that the validation is complete.

   If an application is incomplete, the PM notifies the entity. Before the application is reviewed, the entity revises and resubmits the application until the PM deems it complete. The application processes are iterative in nature and the PM and QECP team will work with each entity to ensure that all pieces of evidence are submitted.
3. Once the application is complete, the review team assesses the entity's submitted evidence and self-assessments against the program's requirements.
4. After the application has been reviewed, if deficiencies are identified, the entity is notified and permitted to resolve them.
5. If no deficiencies are identified during the application review, a recommendation report is sent to CMS, detailing the performance of the entity against the minimum requirements for each review phase.
6. Based on the recommendation report, CMS renders a final decision.
7. The entity receives a CMS decision letter and, if applicable, a list of steps the entity must take to proceed to the next phase of review.

Ongoing Program Administration and Monitoring

As part of **Ongoing Program Administration (OPA),** the QECP team ensures continued compliance with all program elements and requirements and provides continuous support throughout the QE's certification period. Through OPA, the QECP team observes the QE's compliance with all program elements and provides continuous support throughout the QE's certification period. The QECP monitors and addresses any data security breaches, programmatic changes on the part of the QE, annual report submissions, and progress toward the completion of any corrective action required. Once an organization is approved as a QE, they are subject to OPA and monitoring. OPA monitoring consists of 1) QE self-reported changes, 2) QE Annual Report information and attestations, 3) triennial QECP Reapplication

information and attestations, 4) QECP Compliance Monitoring Gray Literature Scans, and 5.) QECP Data Security Audit. These activities are designed to identify potential non-compliance.

When a potential non-compliance issue is identified it triggers a QECP monitoring review. A monitoring review may be conducted for any QE that is found to be out of compliance or at risk of non-compliance with program standards. During the monitoring review, the QECP team assesses a QE's compliance with selected elements related to data security and privacy, the provider corrections and appeals process, and/or performance measures and public reporting. In addition, a QECP Data Security Audit may occur within three years after the QE has received CMS data and every three years thereafter to ensure compliance with the QE data security standards. Data security deficiencies and issues of program non-compliance discovered during audits are referred to the QECP Monitoring Team to review and recommend either **Technical Correction** (TC) or **Corrective Action Plan** (CAP).

In addition, should a data security breach or other violation of the CMS DUA be discovered during an audit, the audit team would immediately direct the QE to report the breach/violation to the CMS IT Service Desk.

During the monitoring review, the QECP contractor assesses whether to advance the matter further and makes its recommendation to CMS. Once CMS approves a next step/plan of action, the QECP contractor may request clarifying information from the QE. After this evidence has been received and reviewed, if a program violation is determined, the contractor recommends one of three monitoring actions: (1) Warning, (2) TC, or (3) request for CAP. A QE may receive any one of the violations as a starting point with the potential to move to a more elevated status should they not meet the terms of the initial violation.

More information about OPA and Monitoring may be found in Section 4: Ongoing Program Administration.

Public Reporting

Within one year of receiving the CMS QE Fee-For-Service (FFS) data, all QEs must release a public report. CMS wants to promote innovation with the report design and dissemination plan with the QECP. The QE is expected to propose a plan for how the measures and providers reported on will reach their target audience. There is no established prototype for the report or the dissemination plan. QEs may not release public reports to providers or to the public until QECP reviewers approve the dissemination approach and the report design. QEs are required to report publicly on all years of data that they received from CMS. QEs should report on all historical years of data requested from CMS in their first public report. Please also note that QE public reporting refers to any public report generated by the QE using the QE Medicare data and approved QECP measures. QEs that are unable to release public reports within one year of receiving QE Medicare data may request a public reporting extension from CMS. However, QEs should note that CMS generally approves only one 1-year extension request. CMS grants extensions on a case-by-case basis, with the expectation that the QE will release its public report by the extended deadline. If a QE receives an extension that is less than one year, the QE will use that new public reporting date to report their QE reporting efforts in the future.

Creating a New Public Report in the QE Application

Once a QE publishes a public report, they should go into their QECP Application to document it. The public reporting tab is accessible through the QE user`s log in screen. The QE user should create a new public report and fill out all the relevant information fields. Once all the information fields are filled out, the QE user should upload a pdf version or screenshots of their published public report. The QE user can then save and submit the report for review. All QEs should submit their public reports within one week of the report being released. For more information about creating a new public report please refer to the public reporting e-learning module on the QECP public website.

Reapplication

QE certification is valid for 3 years, and QEs must reapply at least 6 months prior to their 3-year certification anniversary to continue receiving QE Medicare data under the program. During reapplication, QEs must report changes to previously assessed QECP minimum requirements and submit supporting documentation to confirm the changes. The QE reapplication process requires less time and effort than the initial application process because the reapplication process leverages QE documentation already on file with CMS and requires QEs to respond to a form that has been pre-populated with data from the QE's PM and consists of approximately 10 statements. See Section 5: Reapplication for more information about the reapplication process.

QE Medicare Data

QEs and quasi QEs are eligible to request Medicare Parts A and B claims data and Part D prescription drug event data. QE data extracts are based on the geographic region for which QEs have other sources of claims data. Quasi QE data extracts are determined by the providers affiliated with the QCDR.[1] Data dictionaries can be found here: https://www.ccwdata.org/web/guest/data-dictionaries.

Uses of QE Medicare Data

QEs are required to use QE Medicare data (standardized extracts of Medicare Parts A and B claims data and Part D prescription drug event data) combined with other sources of claims data to generate public reports for providers and suppliers on measures of quality, efficiency, effectiveness, and resource use. QEs may also use the Medicare data to provide or sell non-public reports or combined data, or provide Medicare data at no cost, to certain authorized users. For more information about the permissible uses of data under the QE program, see Section 6: Additional Uses of Medicare Data.

[1] Data extracts for quasi QEs are based on the providers affiliated with the QCDRs. All beneficiaries with at least one claim submitted by a provider affiliated with the QCDR will be included in the data extract. Furthermore, the data extract will contain all claims for those beneficiaries, including claims from other providers.

SECTION 1. PHASE 1: ELIGIBILITY & EXPERIENCE

In Phase 1, the **QECP**[2] examines an **entity**'s organizational structure, its ability to successfully function as a **qualified entity (QE)**, and its access to additional claims **data sources**. Each phase of the QECP minimum requirements review consists of **elements**, or key areas of review and consideration. Each element has an **assessment**, a description of the program requirements and performance expectations with which an entity must demonstrate compliance, as well as **evidence** requirements, or items that an entity must provide in support of the assessment. Phase 1 includes the following elements, described in detail in Exhibit 3:

- Entity (Element 1.1)
- Financial Resources (Element 1.2)
- Experience (Element 1.3)
- Claims Data (Element 1.4)

The Phase 1 **application** is expected to take up to 2 months for the **applicant** to complete and submit. The Phase 1 review, including CMS' final outcome decision, is estimated to take up to 20 business days from the submission of a complete and **validated** Phase 1 application that meets all requirements. QCDRs applying to become **quasi QEs** do not need to demonstrate experience requirements (Element 1.3) or provide evidence that identifies their sources of **clinical data** (part of Element 1.4). Additional information can also be found on the Phase 1 page of the QECP website. The following sections provide more information about the elements in Phase 1.

1.1 Entity, Financial Resources, and Experience

For these elements, entities must present information about their organization, including whether they are applying as a single entity, a subsidiary, or as an entity with partners, vendors, contractors (including any intended Cloud Service Providers (CSPs)) under contract for the purposes of the QECP, and show a commitment to using the **QE Medicare data** for **public reporting**. In terms of financial resources, entities must show an ability to cover the costs of functioning as a QE by providing information about their business model. Finally, entities must generally demonstrate 3 or more years of experience across areas related to provider performance measurement and public reporting.

1.2 Claims Data

This requirement assesses the geographic area(s), level of analysis, data sources, and types of **claims** data to which the entity has access for purposes of QECP performance measurement. Entities must have at least one source of **other-payer claims data** from their relevant geographic areas at the time of application; however, two or more sources of other-payer claims data are preferred. These data must be provider- and supplier-identifiable, and entities must have **full usage rights** for the data. To note, both pre-adjudicated and adjudicated claims data are an acceptable source of other-payer claims data. Entities must demonstrate that their claims data, when combined with the requested QE Medicare data, meet CMS sufficiency thresholds and the requirements for sample size and **reliability** to produce measures based on **combined data**. Additionally, entities are asked to include a statement confirming their intention to request the **5% national sample** for benchmarking purposes, if applicable.

1.3 Phase 1 QE Program Requirements

The elements against which entities will be evaluated for Phase 1 are presented in full in Exhibit 3. The explanation of each element describes the assessment(s) to be performed by reviewers in evaluating an application, along with evidence requirements. To meet the **minimum requirements**, entities must pass

[2] Selected terms in **bold font** are defined in the Appendix A: Glossary.

all assessments. A failure on any assessment may prevent an entity from receiving QE Medicare data for performance measurement and being certified as a QE by CMS.

In Phase 1, entities must complete the forms provided in the application and should also provide any additional documents that demonstrate their ability to meet the requirements of each element. Exhibit 3 identifies examples of documentation for each element, but they are not comprehensive. Entities should contact their QECP PM to discuss other forms of documentation that may be appropriate.

The evidence will be reviewed using the QE online submission process. Upon successful completion of the Phase 1 review, the entity's compliance status will be determined (see Section 1.4) and if qualified, the entity may proceed to Phase 2.

Logo Usage by QEs and quasi-QEs

Only QEs and quasi QEs are permitted to use the "Certified QE" logo provided by the QECP team at the point of Phase 1 certification. QEs are not permitted to modify or change the QE logos. Participants in the QECP and quasi-QE programs are not permitted to display nor use either the U.S. Department of Health and Human Services or Centers for Medicare and Medicaid Services logos due to their participation in the QE program. Parent organizations, subsidiaries, partners, vendors, subcontractors, consultants, and vendors are **not permitted** to use/display the "Certified QE" logo.

Exhibit 3: QECP Minimum Requirements Review: Phase 1 QE Program Requirements

Phase 1: Eligibility & Experience	
QE Program Requirement	**Element**
1.1: Entity	
Assessment	The entity is a legally recognized "**lead entity**" and accountable to CMS for the receipt of QE Medicare data, with clear contractual relationships identified and documented between contractors or member organizations, if applicable, that make it possible to meet the QECP requirements.
Evidence Requirement	1. QECP Letter of Commitment Form, containing: a. Commitment to CMS signed by a member of the lead QE's executive team b. Attestation that QE or quasi QE is committed to releasing a public report within 12 months of receiving data c. *For applicants with contractors, vendors, partners, subsidiaries, or member organizations only*: Completed contractual relationship attestation, which includes attestation of breach of contract liability between parties with potential to collect damages for failure to perform d. *For applicants planning to use a CSP:* Completed Cloud Service Provider Identification, which includes the name of the proposed CSP e. Completed CMS Quality Improvement Organization attestation, if applicable 2. Incorporation and, if applicable, licensure for Lead entity, contractors, vendors, partners, subsidiaries, or member organizations
Example Documentation	• Incorporation or licensure documentation
1.2: Financial Resources	
Assessment	The entity's business model is projected to cover the cost of public reporting, including costs of the data, and developing the reports. When planning financial resources for the QECP, entities should also consider data infrastructure and maintenance fees and staffing resources to meet QECP application and ongoing program administration requirements. Please note that, while important, it is not a requirement to reflect these items in the entity's business model.
Evidence Requirement	1. Description of entity's business model and resources to support the cost of the data and developing the reports. The business model should include line items specifically for the cost of the CMS FFS data and the cost of producing and releasing a public report. 2. An allocation of necessary resources to successfully participate in the program on an ongoing basis and evidence around the QE's business model, specifically, evidence of sources of sustainable income. This can be submitted as a narrative, supplemental budget, or business plan documentation. ***Note**: Evidence must come from the lead entity, not from a contractor or member organization.*

Phase 1: Eligibility & Experience	
QE Program Requirement	**Element**
1.1: Entity	
Example Documentation	• Business plan • Project budget • Grant award • Letter from a signatory or the board of your organization

1.3: Experience	
Assessment	The entity generally demonstrates 3 or more years of experience in combining claims data, accurately calculating measures, verifying data, public reporting, and using a corrections process. ***Note**: QCDRs applying to become quasi QEs are exempt from compliance with Element 1.3.*
Evidence Requirement	For each applicable area below, the entity: a) attests to meeting the requirement, and b) provides a description that generally demonstrates 3 or more years of expertise and experience. Description may include methods used for previous reporting efforts. 1. Combining claims data: Describe expertise and experience successfully combining claims data from different payers (at least two) to calculate performance reports. If the entity has experience combining Medicare claims data with claims from other sources, please include in the description. 2. Attribution of patient services and episodes: Describe experience and expertise with attribution of patient services or episodes to specific providers or suppliers. 3. Statistical validity – quality measures, *applicable only if the entity selects quality measures to evaluate providers*: Describe experience and expertise establishing statistical validity requirements for quality measures, such as minimum number of observations or minimum denominator size. 4. Statistical validity – efficiency or resource use measures, *applicable only if the entity selects efficiency or resource use measures to evaluate providers*: Describe experience and expertise establishing statistical validity of efficiency and resource use measures, such as minimum number of observations or minimum denominator size or a standard payment methodology where appropriate. 5. Risk adjustment: For each type of measure (e.g., quality, efficiency, and resource use) the entity plans to use to evaluate providers, describe experience and expertise using methods for risk adjustment to account for variations in both case mix and severity among providers and suppliers. If the entity does not use or plan to use risk adjustment, provide a justification. 6. Outliers: For each type of measure (e.g., quality, efficiency, and resource use) the entity plans to use to evaluate providers, describe experience and expertise identifying methods for handling outliers. If the entity does not use or plan to use outlier methods, provide a justification. 7. Defining comparison groups (e.g., individual clinicians, clinic, or group/practice), *applicable only if the entity will use comparison groups to evaluate providers*: Describe expertise and experience developing appropriate peer groups of providers and suppliers for meaningful comparisons. 8. Verification process: Describe expertise and experience in implementing a quality assurance process including assessing measure reliability and correcting errors. 9. Public reporting: Describe experience and expertise: a. Accurately preparing performance reports on providers and suppliers and making such performance reports available to the public b. Designing and continuously improving the format of performance reports on providers and suppliers, such as testing with users and use of evaluations to improve reporting c. Developing 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 10. Corrections process, applicable only if the entity will identify providers and suppliers in their QE reports. * Describe experience and expertise: a. Implementing and maintaining a process for providers and suppliers identified in a report to review measure results prior to publication

	b. Providing a timely response to provider and supplier inquiries regarding requests for data, error corrections, and appeals **Corrections and appeals experience is not required if the entity plans to report regionally (providers are de-identified) and seek a corrections and appeals waiver. However, entities will not be permitted to conduct **any** corrections and appeals processes, for public or non-public analyses, without meeting this requirement.* ***Note**: Evidence of experience may include the demonstrated experience of the applicant, the applicant's contractor(s), or, if the applicant is a collaborative, any member of the collaborative. QEs may also use the experience of individuals within their organization or its contractors' or members' organizations to satisfy experience requirements.*
1.4 Claims Data	
Assessment	The entity defines the geographic area(s) and level of analysis for which public reporting will incorporate QE Medicare data and possesses claims data from at least one other source; however, data from two or more sources is preferable. ***Note:** QCDRs applying to be quasi QEs are not required to provide evidence that identifies their sources of clinical data; however, they must provide information about the total number of providers that are regularly providing data to their registry, the level of analysis for public reports, and whether they intend to request a 5% national sample for benchmarking.*
Evidence Requirement	11. Completed QECP Data Source Attestation, containing: a. Description of the geographic areas the entity's report(s) will cover b. Level of analysis for QE public reports (regional or provider-identified) c. Data supplier profile, including data suppliers' names and dates of agreement for the largest 5 suppliers and aggregate information on the remaining (if applicable) d. Data detail i. Volume of data ii. Geographic coverage of data e. Data description i. Claims data adjudication status ii. Medicare Advantage covered lives iii. Volume of pharmacy claims data received, if applicable f. Covered lives calculator i. Total number of covered lives included in all other-payer claims data sources (by state if reporting nationally or by county if reporting for a region smaller than a state) 12. As applicable, an entity's PM may ask for further clarification on how the applicant's other-payer claims data will adequately address concerns of small sample size and reliability. 13. Explicit statement for 5% national sample, if applicable.
Example Documentation	Completed QECP Data Source Attestation, supported by documents such as: • State or federal statutes • Documents supporting the adequacy of the combined data set • Spreadsheets, lists

1.4 Phase 1 Outcomes

After Phase 1 of the minimum requirements review, a certification decision is rendered. There are two possible outcomes: *Qualified* and *Not Qualified*.

1.4.1 Phase 1: Qualified

An entity receives the status *Qualified* if it demonstrates complete compliance with the requirements of Phase 1 of the application and then is considered a certified QE. This status is valid for 3 years from the date of notification of CMS approval unless a QE's status is otherwise terminated (see Section 5.4). With permission from the QE, CMS will announce the entity's certification as a QE on the Qualified Entity Program website (http://www.cms.gov/QEMedicareData) and will also add your organization to the Certified QE Map on the QE Program website (http://www.qemedicaredata.org).

After certification, QEs must submit their evidence for Phases 2 and 3 of the minimum requirements review. QEs must also work with ResDAC, the Chronic Conditions Data Warehouse (CCW), and CMS to submit QE Medicare data requests and pay fees to receive annual and/or quarterly updates of QE Medicare data. To maintain QE certification status, QEs must reapply every 3 years. QEs must submit their reapplication six months prior to their 3-year certification anniversary.

1.4.2 Phase 1: Not Qualified

An entity receives the status *Not Qualified* if it has not demonstrated complete compliance with the requirements of Phase 1 of the application. Failure on any single element will result in an outcome of *Not Qualified*.

An entity that receives an outcome of *Not Qualified* may submit a second application within a 12-month period from the date of the CMS decision letter, but no sooner than 90 business days after the date of the letter. If the entity again receives the status of *Not Qualified*, it must wait 12 months from the date of the second letter to reapply.

SECTION 2. PHASE 2: DATA SECURITY AND CORRECTIONS AND APPEALS

In Phase 2, the QECP evaluates the QE's compliance with the data security, privacy and corrections and appeals requirements of the program.

The Phase 2 application is expected to take up to 4 months for the QE to complete and submit. The Phase 2 review, including CMS' final outcome decision, is estimated to take up to 20 business days from the submission of a complete and valid Phase 2 application that meets all requirements. The time period is highly dependent on the QE's access to, and submission of, the requested artifacts.

In Phase 2, QEs must provide evidence in the areas of data security, privacy and corrections and appeals as described in Sections 2.1–2.4 below. Information on the **CMS data use agreement (DUA)** request process can be found in Section 2.6.

2.1 Data Security and Privacy

QEs must demonstrate that they have rigorous security and privacy practices in place to protect Medicare data. The CMS DUA specifies that QEs must establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the QE Medicare data and to prevent unauthorized use or access to it. Every contractor or organization within the QE that hosts beneficiary identifiable data must adhere to the controls, policies, and procedures under the QECP Data Security Review.

The QECP employs program appropriate controls from the CMS technical standard **Acceptable Risk Safeguards (ARS)** as the standard to assess the QE's compliance with QECP Requirements. The CMS ARS are included in the Phase 2 Toolkit.

2.2 Intentions Regarding Non-Public Analyses

During Phase 2, QEs must attest to their intentions to provide or sell provider-identifiable non-public analyses to **authorized users**. Any reports that are provider-identifiable must go through the corrections and appeals process described in Section 2.3 below.

2.3 Provider Corrections and Appeals, and Secure Transmission of Beneficiary Data

If QEs choose to report at a provider-identifiable level, they are required to share confidentially the performance results with the providers that are being evaluated and to allow for corrections prior to reporting. This applies for results contained in either public reports or non-public analyses to be provided or sold to authorized users. For each measure used, QEs must provide the measure name and description, methodology, and results to providers prior to public and non-public release. QEs must give providers advance notice of the date the reports will be made public and must accept requests for corrections and appeals from providers for the entire 60 or 65 calendar days. The table below delineates the various timelines for a corrections and appeals process. QEs may release Medicare beneficiary names to providers only when such information is relevant to the particular measure or measure results the provider is appealing. QEs must release reports on the specified date regardless of the status of any requests for error correction. If the QE chooses to report aggregated results in which providers are not identified, for both its public reports and its non-public analyses, a corrections and appeals process is not required, and the QE will be exempt from Elements 2.3 and 2.4. Should a QE determine at a later date once they have already completed the Phase 2 application that they wish to report at a provider-identifiable level for either public or non-public analysis, evidence for Element 2.3 will need to be resubmitted.

Requirements for Corrections and Appeals of Provider-Identifiable Analyses	
Public Reports	**Non-Public Reports**
Shared with providers to accommodate corrections and appeals at least **60 calendar days** prior to release.	Shared with providers to accommodate corrections and appeals at least **65 calendar days** prior to delivery/finalization

Please note that the decisions a QE makes to comply with requests for corrections or appeals will have an impact on compliance with its data security and privacy plan.

If a QE does not plan on identifying providers in their public report, they must submit masking methodology under Element 2.3 to show QECP reviewers how their report will prevent reidentification of providers. QEs are permitted to publicly report performance measures that are aggregate or otherwise de-identified at the provider-level (e.g., individual physician, clinic, practice, medical system, etc.). However, the QE must provide detailed evidence in Phase 2 explaining how measure results could not be associated with a particular provider or provider group. This evidence must explain the QE's provider-masking methodology and specifically indicate how this methodology prevents provider-level performance from being re-identified in QE reports. CMS will review the QE's provider masking methodology and determine whether the QE is eligible for a QE provider corrections and appeals waiver.

QEs that are planning to report at the regional or provider deidentified level must submit masking methodology to Element 2.3 but are exempt from Element 2.4.

Quasi QEs are exempt and are not required to submit evidence for requests for corrections or appeals if they intend to publicly report measures through Care Compare that were included in the QCDR self-nomination process and the measures are calculated from a combined data set of CMS claims and clinical data sources. If measures are ineligible for Care Compare public reporting, or if they are QECP standard or approved alternative measures, quasi-QEs may have to perform corrections and appeals, depending on the level of reporting. Quasi QEs intending to engage in non-public analyses at the provider level must submit a corrections and appeals process.

During the 3-year QE certification period, if QEs alter their public reports and/or corrections and appeals process, it may be necessary for QECP reviewers to assess and approve the QE's updated dissemination plan and public reports. QEs may not release public reports to providers for the corrections and appeals process until their final dissemination approach and public report prototypes are approved.

2.4 Phase 2 QE Program Requirements

QEs that are planning to engage in a provider corrections and appeals process must demonstrate how they will securely transmit beneficiary data if the provider requests a correction. This process should be detailed in your data flow diagram and in your Data Security Review. Exhibit 4 further details how the QE will be evaluated under element 2.4.

Exhibit 4: QECP Minimum Requirements Review: Phase 2 QE Program Requirements

Phase 2: Data Security	
QE Program Requirement	**Element**
2.1: Data Security Review	
Assessment	The QE demonstrates its ability to comply with federal data security and privacy requirements, and documents its processes to follow protocols for the following CMS ARS controls (**control family** abbreviations in parentheses): • Access Control (AC) • Authority and Purpose (AP) • Awareness and Training (AT) • Audit and Accountability (AU) • Security Assessment and Authorization (CA) • Configuration Management (CM) • Contingency Planning (CP) • Identification and Authentication (IA) • Incident Response (IR) • Maintenance (MA) • Media Protection (MP) • Physical and Environmental Protection (PE) • Planning (PL) • Personnel Security (PS) • Risk Assessment (RA) • System and Services Acquisition (SA) • System and Communications Protection (SC) • System and Information Integrity (SI) • Program Management (PM) • Accountability, Audit, and Risk Management (AR) • Data Quality and Integrity (DI) • Data Minimization and Retention (DM) • Individual Participation and Redress (IP) • Security (SE) • Transparency (TR) • Use Limitation (UL)

Phase 2: Data Security	
QE Program Requirement	**Element**
2.1: Data Security Review	
	For detailed descriptions of the security controls listed above, please review the ARS Publication that is saved in the Phase 2 toolkit.
Evidence Requirement	1. Completed *QECP Data Security Review* supported by the following context documents: a. Policy and procedure documents that have been reviewed and updated within the past 3 years for the following five families: AC, IA, MP, SA, and SI. b. Data flow diagram with annotations that describe the flow and management of QE Medicare data through the system and the documents and partner organizations involved. The data flow diagram must also describe the identified or deidentified state of the CMS data in each stage of the data management process. See the example data flow diagram included in Phase 2 toolkit. c. List of past data security breaches over the past 10 years d. If the QE is going to utilize a CSP to store or manage the QE Medicare data, an executed Business Associate Agreement (BAA) between the QE and the CSP that demonstrates an understanding of the nature of data being stored, processed, and transmitted to/from the CSP. The CSP must be FedRamp certified as well as have an Authority to Operate (ATO) with CMS.

2.2: Intentions Regarding Non-Public Analyses	
Assessment	If an entity intends to provide or sell non-public analyses to an authorized user that individually identifies a provider or supplier, the entity will follow program requirements and submit appropriate evidence for the corrections and appeals process.
Evidence Requirement	1. If your organization intends to provide or sell non-public analyses to an authorized user that contains information that individually identifies a provider or supplier please refer to the reminders below for a **yes** or **no** response: If yes, please note the following reminders: a. QEs must follow the requirements in 42 CFR § 401.716 and the corrections and appeals process as outlined in § 401.717(f). b. QEs must describe their process for corrections and appeals in Element 2.3 and their methods for ensuring that only the minimum necessary beneficiary identifiers and/or claims data are transmitted to providers in Element 2.4. c. QEs must ensure that they have provided evidence of experience with the corrections and appeals process under Element 1.3. If this information was not provided during Phase 1, it should be completed at this time. 2. If no, please note the following reminders: a. QEs must describe their process for provider-masking methodology and specifically indicate how this methodology prevents provider-level performance from being re-identified. b. If a QE would like to engage in provider-level non-public analyses in the future, they will need to submit a full corrections and appeals process to be reviewed by the QE team prior to releasing those reports to authorized users.
2.3: Provider Corrections and Appeals	
Assessment	If providers or suppliers will be identified in QE reports (public and, if applicable, non-public analyses), the QE has an established process that allows providers to view reports confidentially, request data, and ask for correction of errors. If providers will be de-identified in QE public reports, the QE has a process for ensuring that any published measure results could not be associated with a particular provider.
Evidence Requirement	1. If providers or suppliers will be identified in QE reports (public and if applicable, non-public analyses): Describe the process the QE will use to allow providers and suppliers to view reports confidentially, request data, and ask for the correction of errors before the reports are made public or disclosed to the authorized user (for non-public analyses). ***Note:*** *For QE public reports, the data must be shared with the provider at least 60 calendar days prior to publicly reporting results. For non-public analyses, QEs must allow providers and suppliers the opportunity to opt into the review and corrections process for 65 calendar days.* 2. If providers will be de-identified in QE public reports: Explain the QE's provider-masking methodology and specifically indicate how this methodology prevents provider-level performance from being re-identified in QE reports. ***Note****: The QECP team does not review provider masking methodologies for non-public analyses (only for public reports). It is the QE's responsibility to review the requirements at 42 CFR § 401.716 to determine whether a corrections and appeals process, as outlined in §401.717(f), is required.*
Example Documentation	• Process documents • Standard operating procedures • Process/flow charts ***Note:*** *If a provider or supplier has a data or error correction request outstanding at the time the reports are released, the QE must, if feasible, post publicly the name of the appealing provider or supplier and the category of the appeal request.*

2.4: Secure Transmission of Beneficiary Data	
Assessment	The QE has established a process that applies privacy and security protections for the release of beneficiary identifiers, claims data, or both, to providers for the purposes of the requests for corrections/appeals.
Evidence Requirement	Provide artifacts that explain the processes and procedures associated with the secure transmission of beneficiary data, including a description of the process ensuring that only the minimum necessary beneficiary identifiers, claims data, or both will be disclosed in the event of a request by a provider. In addition, please provide the method for secure transmission and the entity responsible for secure transmission of data. Include within the annotation states for the data flow diagram narratives that explain the following: a. How the QE will verify that only the appropriate representatives within a provider group are permitted to access PII in the event of a request for correction b. How access credentials to PII are communicated to appropriate representatives within each provider group and how authorized representatives may create additional access accounts for (and communicate credentials to) additional authorized individuals within their provider group c. How only the minimum necessary beneficiary identifiers and claims data will be disclosed to providers who request data d. The mechanism used to transmit beneficiaries' PII to providers in the event of a request for correction e. The name of organization/contractor responsible for transmitting beneficiaries' PII to providers in the event of a request for correction
Example Documentation:	• Data Flow Diagram that incorporates the processes to engage providers (either through electronic or postal mail).

2.5 Phase 2 Outcomes

There are two possible outcomes for Phase 2: *Compliant* and *Non-Compliant*. ***Compliant Phase 2 review outcomes do not provide a CMS endorsement, nor do they validate the sufficiency of the QE's data security and privacy program for purposes outside of the QECP***.

2.5.1 Phase 2: Compliant

If the QE is found to be *compliant* with the Phase 2 requirements, it may begin the process to request and pay for Medicare data and enter into a DUA with CMS (described in Section 2.6).

QECP Phase 2 outcomes are based solely on the information QEs provide to CMS at the time of the Phase 2 review. There is no expressed guarantee regarding the future performance of a QE because new system, personnel, and environmental vulnerabilities and threats are continually evolving. It is the responsibility of the QE to continuously comply with the CMS DUA and maintain a data security and privacy program that is compliant with the ARS version currently being utilized by the QECP.

2.5.2 Phase 2: Non-Compliant

If a QE is found to be *non-compliant* with the Phase 2 requirements, the review team will work with the QE to determine an appropriate timeline for corrections and the resubmission of evidence to satisfy all mandatory data security controls. If the QE is unable to meet all mandatory data security controls, its QE certification status may be terminated.

2.6 Medicare Data: Applying for Access and Data Delivery

Once a QE successfully completes Phase 2, it can request QE Medicare data. Prior to reaching out to the DUA Contractor (ResDAC) QEs can work with their PM to schedule a pre-DUA call to address any questions. During this call, the team can address any questions about the DUA process and review the required documents (listed below):

- QE Data Use Agreement (DUA): https://resdac.org/request-materials/qe-data-use-agreement-dua
- QE Specifications Worksheet: https://www.resdac.org/request-materials/qe-specifications-worksheet

2.6.1 Applying for Access to Medicare Data

Upon notification of Phase 2 compliance, the QE can submit a data request package to ResDAC, for approval. Prospective applicants may obtain a preliminary estimate of the cost of acquiring QE Medicare data by visiting the Data Cost Estimates Page on the QECP public website.[3] The QE will receive a formal cost invoice once the DUA is approved.

The ResDAC website (https://www.resdac.org) contains descriptions of available CMS data, data request procedures, information on workshops on how to use Medicare data, and other helpful resources. Within approximately 10 business days of submission of the data request packet to CMS, a CMS privacy analyst will notify the QE by email of CMS' approval of the data request.

Together with the notification that CMS has approved the DUA, the QE will receive instructions on how to submit payment for the requested data files. Payment is due within 5 business days of receiving the

[3] https://www.qemedicaredata.org/apex/Data_Availability_and_Cost

final invoice. Data will be prepared and released to QEs only after payment has been successfully processed.

QEs work directly with the DUA Contractor during the data request process. ResDAC provides resources and technical support on its website and by email and phone. The website provides information on the data available, how to request QE data, relevant data dictionaries, workshops, and webinars.

- DUA Contractor's QE website: https://www.resdac.org/requester/qualified-entity
- DUA Contractor's contact email: resdac@umn.edu
- Toll-free Helpline: 1-888-9RESDAC (1-888-973-7322)
- DUA Contractor workshops: https://www.resdac.org/learn

2.6.2 Making Changes to DUA

Making Changes to Individuals listed on your DUA

QEs should work directly with the QECP CMS Contacts, Kari Gaare (kari.gaare@cms.hhs.gov) and Linh Kennell (linh.kennell@cms.hhs.gov) to make changes to individuals listed on a DUA. All requests sent to CMS should include Kari Gaare, Linh Kennell and qecp_dua@index-analytics.com for review and approval. For more information about adding or removing an individual from a DUA, please see the CMS website.

Adding Additional Years of Data to your DUA

QEs wanting to add additional years of data to their DUA should work directly with the staff at ResDAC to submit updated documentation, receive their cost invoice, and have their request approved by CMS. QEs must use all years of data requested in public reporting.

2.6.3 Receiving the CMS Data

While the DUA contractor serves as the primary point of contact for CMS data requestors and users, specific questions about the data files received from the CCW contractor (HealthAPT) should be directed to CCW staff, who provide technical assistance to QEs. The CCW website offers several resources for QEs, including summary statistics for comparative analysis, data dictionaries for each file type, user guides, technical papers on producing prevalence rates, and other analytical guidance documentation.

- CCW website: http://www.ccwdata.org
- CCW technical assistance email: CCWhelp@gdit.com
- Toll-free Helpline: 1-866-766-1915
- Data dictionaries for CCW data sets: https://www.ccwdata.org/web/guest/data-dictionaries

SECTION 3. PHASE 3: DATA INTEGRATION & MEASURE CALCULATIONS

During Phase 3, the QECP team assesses the QE's compliance with the remaining program requirements related to the QE's measurement and reporting activities. Prior to submitting evidence for the Phase 3 review, the QE must integrate the QE Medicare data with its claims data from other sources and calculate provider measures. This section of the guide presents the evidence requirements against which entities will be evaluated in Phase 3.

The Phase 3 application, including integration of the data, is expected to take up to 10 months for the QE to complete and submit. The Phase 3 review, including CMS' final outcome decision, is estimated to take up to 25 business days from the submission of a complete and valid Phase 3 application that meets all

requirements. After a QE is recognized by CMS as Phase 3 compliant, the QE begins the confidential 60-day provider corrections and appeals process, if applicable.

There are different Phase 3 and public reporting requirements depending on the measures quasi QEs use. Quasi QEs can use the measures publicly reported through Care Compare to satisfy the QE public reporting requirements if the measures were included in the QCDR self-nomination process and they are calculated from a combined data set of CMS claims and clinical data sources. If a quasi QE chooses to report only via Care Compare, it will be exempt from Phase 3.

In order to receive a Phase 3 evidence exemption, quasi QEs must submit a list of measures that they intend to publicly report. This list will be reviewed to verify that each measure was included in the quasi QE's QCDR self-nomination process and that the measure can be calculated using combined data. Once Care Compare is updated, quasi QEs must submit evidence to the QE program of all the quasi QE's self-nominated measures that were published by Care Compare. If Care Compare does not report any of the quasi QE's self-nominated measures, the quasi QE then has six months to choose another pathway, submit any necessary evidence, and publicly report.

If a quasi QE's self-nominated measures that are calculated from a combined data set of CMS claims and clinical data sources do not meet Care Compare public reporting requirements, then the quasi QE will be required to publicly report the measure(s) in order to satisfy the public reporting requirement. If a quasi QE plans to only report standard or approved alternative measures through a public-facing reporting mechanism (such as the quasi QE's public website), a full Phase 3 review will be required.

Quasi QE Phase 3 Requirements and Options for Satisfying Public Reporting Options		
Quasi QE reports only measures that were included in the QCDR self-nomination process and are calculated from a combined data set of CMS claims and clinical data sources via:		**Quasi QE reports only QECP standard or approved alternative measures via a public-facing reporting mechanism (e.g., quasi QE's website)**
Care Compare[4]	***Other public reporting mechanism (e.g., quasi QE's website)***	
Quasi QE is eligible for a Phase 3 exemption[5]	Quasi QE must provide a public report prototype (Element 3.3) but is otherwise exempt from Phase 3	Quasi QE must complete all elements in Phase 3

In Phase 3, QEs must provide evidence in the areas described below in Sections 3.1–3.3. More information on this phase can be found on the Phase 3 page of the QECP website.

[4] Note: If measure(s) do not meet Care Compare public reporting requirements (first year measures, etc.), the quasi QE will be required to publicly report the measure(s) in order to satisfy the public reporting requirement.

[5] In order to receive a Phase 3 evidence exemption, quasi QEs must submit a list of measures that they intend to publicly report. This list will be reviewed to verify that each measure was included in the quasi QE's QCDR self-nomination process and that the measure can be calculated using combined data.

3.1 Performance Measures Selection

In Phase 3, the QE is required to identify the measures that will be calculated with QE Medicare data and included in its QE public report. Please note that during Phase 3, evidence requirements for quasi QEs may differ.[6] For the purposes of the program, **standard measures** are claims-based measures that are calculated in full or in part from **standardized extracts** of Medicare Parts A and B claims data and Part D prescription drug event data. They include all performance measure types, such as **quality measures** (structure, process, and outcome measures), **resource use measures**, **efficiency measures**, and **composite measures**. Generally, QEs use standard measures for evaluating the performance of providers or the quality of care for a particular geographic region. QEs may also choose **alternative measures**; however, if they do, they must provide additional evidence, including an explanation of why the alternative measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use than the standard measure. More information about standard[7] and alternative measures[8] can be found on the QECP public website.

3.2 Methodology for Measurement and Attribution

During Phase 3, the QE must describe how it will ensure accuracy of the quality, efficiency, or resource use measures it intends to calculate using QE Medicare and other claims data. This requirement includes, for example, assessing the QE's ability to follow measure specifications, use a defined and transparent method for the **attribution of patient services and episodes**, and define and identify appropriate peer groups and benchmarks. The element further assesses whether, as specified and based on the QE's available claims data (including the received QE Medicare data), the proposed measures meet required scientific properties, for example, sufficient sample size, **reliability**, and **validity.**[9]

3.3 Report Prototypes

During Phase 3, the QE is required to submit prototypes of the confidential provider performance report (if applicable) and the public reports, including the narrative language the QE plans to use in the public reports to describe the data and results. The QE must also provide a dissemination plan for its public reports. QEs should attribute the use of the Medicare Data to their participation in the QE program and should provide the full geographic region for which they are reporting on the Medicare data.

QEs may not release public reports to providers or to the public until QECP reviewers approve the dissemination approach and the report design. If at any time after initial approval the QE wishes to change its dissemination plan or public report design, CMS requires at least 30 days to review and approve the updated plans and public report prototype prior to the QE's next corrections and appeals cycle (see Section 4.2).

[6] Quasi QEs are exempt and not required to submit evidence for measure selection if they intend to publicly report only those measures that were included in the QCDR self-nomination process, and the measures are calculated from a combined data set of CMS claims and clinical data sources.

[7] Standard Measures: https://www.qemedicaredata.org/apex/Standard_Alternative_Measures

[8] Alternative Measures: https://www.qemedicaredata.org/apex/Standard_Alternative_Measures

[9] Quasi QEs are exempt and not required to submit evidence for their methodology for measurement and attribution, if they intend to publicly report only those measures that were included in the QCDR self-nomination process, and the measures are calculated from a combined data set of CMS claims and clinical data sources.

3.4 Reporting Extension Policy

QEs are required to release their first public report within 1 year of receipt of QE Medicare data. If a QE cannot meet this deadline, it may request a public reporting extension from CMS. However, QEs should note that CMS generally approves only one 1-year extension request. An approved public reporting extension request will change the QE's public reporting date for all future public reports. If a QE's original public reporting date is January 1st and they are granted a six-month extension; all future public reports will be due on June 1st. CMS grants extensions on a case-by-case basis, with the expectation that the QE will release its public report by the extended deadline.

3.5 Phase 3 QE Program Requirements

The requirements against which entities will be evaluated for Phase 3 are presented in full in Exhibit 5. The explanation of each element describes the assessment(s) to be performed by reviewers in evaluating an application, together with the evidence requirements. To meet the requirements, entities must pass all assessments.

There is one set of evidence requirements for use with standard measures (Elements 3.1–3.1.g), and a separate, longer set of evidence requirements for use with alternative measures (Elements 3.2–3.2.j).

Exhibit 5: QECP Minimum Requirements Review: Phase 3 QE Program Requirements

Phase 3: Data Integration & Measure Calculations	
QE Program Requirement	**Element**
Performance Measures: Standard Measures ONLY	
3.1: Standard Measure Use	
Assessment	The QE selects standard measures for incorporating QE Medicare data.
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook* (for each standard measure to be included in QE reports), including: a. NQF-endorsed measure number or CMS measure name or number b. Name of measure c. Type of measure (individual, component of composite, or composite) d. Name of measure steward/owner e. Rationale for selecting measure f. Relationship of the measure to existing measurement efforts g. Relevance of the measure to the population in the covered geographic area defined under Element 1.4 in Phase 1
3.1.a: Measure Specifications	
Assessment	The QE uses measure specifications accurately for selected standard measures, including numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.
Evidence Requirement	1. Completed attestation in the *QECP Measure Information Workbook* that standard measure specifications were followed when calculating each measure. ***Note**: If a measure does not follow the exact standard measure specification, it will be considered an alternative measure.*
3.1.b: Statistical Validity for Quality, Efficiency, Resource Use, and Composite Measures	
Assessment	For reporting standard quality measures using QE Medicare data, the QE uses only measures with at least 30 observations, or for which the calculated confidence interval is at least 90%, or the measure reliability is at least 0.70. For reporting standard efficiency, resource use, and composite measures using QE Medicare data, the QE only uses measures with demonstrated reliability and validity, including a standardized payment or pricing approach, if applicable.

Evidence Requirement	1. Completed attestation in the *QECP Measure Information Workbook* indicating the QE followed the statistical validity requirements for selected quality, efficiency, resource use, or composite measures.
3.1.c: Attribution	
Assessment	The QE applies an appropriate method to attribute a particular patient's services or episodes to specific providers or the relevant reporting group. Note: If the selected measures will not be reported at the provider level, the QE must attest to using appropriate attribution levels for the reporting level of choice (i.e., zip code of the episode of care)
Evidence Requirement	1. Completed items within the *QECP Measure Information Workbook*, including a description of the methodology used to assign patients, episodes, or both to the provider included in the performance reports. ***Note**: If methods for attribution of patient services or episodes vary across the measures, this should be noted and described accordingly.*
3.1.d: Risk Adjustment and Outliers	
Assessment	The QE provides a rationale for using or not using: 1) a risk adjustment method and 2) an approach to outliers for standard measures. ***Note**: The QE is required to submit evidence only if it selects a measure that specifies a risk adjustment or outlier method.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook,* including: a. Indication (yes/no) of whether each standard measure employed a risk adjustment or outlier method i. If no, provide rationale for not using a method. b. Attestation that the requirements for risk adjustment and outliers were consistent with the calculation of standard quality, resource use, and composite measure(s)
3.1.e: Comparison Groups	
Assessment	The QE defines the comparison groups it uses to report results for each selected standard measure. ***Note**: The QE is required to submit evidence only if it plans to use comparison groups to evaluate providers.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure to be included in QE reports, the QE must include: a. A general description of the algorithm used to identify comparison groups (e.g., groups are compared by clinic for clinics with three or more practicing physicians) b. The geographic parameters that were used to compare providers to their peers. (e.g., North region includes counties A, B, and C)
3.1.f: Benchmarks	
Assessment	The QE defines the benchmarks it uses to report results for each selected standard measure. ***Note**: The QE is required to submit evidence only if it plans to use benchmarks.*

Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook*. For each measure to be included in QE reports, the QE must include: a. A general description of the type of benchmark used (e.g., national or regional 90th percentile, national or regional average) b. How the benchmark was identified or estimated (e.g., benchmark from federal, state, or community report, or calculated by averaging all the physician rates included in the performance report)
3.1.g: Rating Approaches	
Assessment	The QE uses valid methods for determining and calculating ratings (e.g., stars, or good/ better/best). ***Note**: The QE is required to submit evidence for this element only if measure calculations are aggregated or used to report provider ratings (e.g. stars, or good/ better/ best).*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* A detailed description of the rating approach(es), including rating calculation and statistical methods used. ***Note**: A screenshot from the public report that shows this information is not sufficient evidence for this item*.
3.1.h: Prevalence Rates	
Assessment	The QE uses prevalence rates to show proportion of persons in a population who have a particular disease or attribute at a specified point in time or over a specified period. QEs can only use prevalence rates that include Medicare data if they are associated with an approved quality measure. Note: The QE is required to submit evidence only if it plans to report prevalence rates.
Evidence Requirement	**1.** Completed items in the *QECP Measure Information Workbook.* For each measure to be included in QE reports, the QE must include justification for how this prevalence rate is associated to the alternative measure.
Performance Measures – Alternative Measures ONLY	
3.2 Alternative Measure Use	
Assessment	The QE proposes alternative measures incorporating QE Medicare data. Composite measures are considered alternative measures even if they combine standard measures, unless the standard measure itself is a composite. For alternative measures, the QE demonstrates 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, through consultation and agreement with stakeholders in the QE's community or through the notice and comment rulemaking process.
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook* (for each alternative measure to be included in QE reports), including: a. Name of measure

	b. Type of measure (individual, component of composite, composite) c. Name of measure steward/owner d. Measure description and specifications, including numerator and denominator e. 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 f. Relationship of the measure to existing measurement efforts g. Relevance of the measure to the population in the covered geographic area defined in Element 1.4 in Phase 1 2. Documentation of consultation and agreement with stakeholders in the QE's community, 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 the notice and comment rulemaking process approval.
Example Documentation	• Documents supporting the rationale, relationship, and relevance of selected measures.

3.2.a: Measure Specifications	
Assessment	The QE uses measure specifications accurately for selected measures, including numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook*. For each alternative measure listed include: a. Hyperlink, URL, or copy of the measure specification from the measure steward b. Hyperlink, URL, or copy of the measure specification for implementation (if different from the measure steward's specification) c. Clinical logic (e.g., denominator eligibility, numerator eligibility, exclusion criteria) d. Construction logic (e.g., trigger start dates, temporal parameters) e. System input/output reports/logs for each measure displaying data sources, exclusion statements, denominator values, and numerator values
Example Documentation	• Measure specifications
3.2.b: Statistical Validity for Quality Measures	
Assessment:	For reporting quality measures using QE Medicare data, the QE 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. ***Note**: The QE is required to submit evidence only if it selects quality measures.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure listed in the workbook, the QE must include: a. Description of the minimum requirements for reporting each quality measure that incorporates QE Medicare data, including one of the following: minimum sample size (or denominator size) requirements, minimum calculated confidence interval, or minimum reliability score requirements b. Results of statistical validity testing for each quality measure to be included in QE performance reports, including the actual sample/denominator size, confidence interval, or reliability score
Example Documentation:	• Methodology papers or documents demonstrating the requirements to establish statistical validity of measure results for quality measures
3.2.c: Statistical Validity for Efficiency and Resource Use Measures	
Assessment	For selected efficiency and resource use measures using QE Medicare data, the QE only uses measures for which reliability and validity are demonstrated. For selected efficiency and resource use measures using QE Medicare data that use a standardized payment or pricing approach, the QE provides the specified standardized payment methodology actually being used. ***Note**: The QE is required to submit evidence only if it selects efficiency or resource use measures.*

Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure listed, the QE must include: a. Description of the minimum requirements for reporting each efficiency and resource use measure that incorporates QE Medicare data, including the minimum calculated confidence interval or reliability score b. Results of statistical validity testing for each efficiency and resource use measure to be included in QE performance reports, including the actual sample/denominator size and reliability score, confidence interval, or both c. Description of the standardized payment or pricing approach, if appropriate
Example Documentation	• Methodology papers or documents demonstrating requirements to establish statistical validity of measure results for efficiency and resource use measures.
3.2.d: Statistical Validity for Composite Measures	
Assessment	For reporting composite measures using QE Medicare data, the QE describes the measures that make up each composite. ***Note**: The QE is required to submit evidence only if it selects composite measures. Evidence must be provided for each component measure included in composite measures.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook*, including: a. Construction of the composite i. List of measures ii. Weight of each measure *Note: If measures are weighted differently, provide rationale* iii. Calculation of composite (e.g., take average of all rates and divide by number of measures or all-or-none scoring) b. Description of the minimum requirements for including or excluding a measure within the composite measure
Example Documentation	• Methodology papers or documents demonstrating requirements to establish statistical validity of measure results for composite measures.
3.2.e: Attribution	
Assessment	The QE applies an appropriate method to attribute a particular patient's services or episodes to specific providers. Note: The attribution methodology is still necessary for measures that will be calculated at a regional level.
Evidence Requirement	1. Completed items within the *QECP Measure Information Workbook*, including a description of the methodology used to assign patients and/or episodes to the provider included in the performance reports. ***Note**: If methods for attribution of patient services or episodes vary across the measures listed, this should be noted and described accordingly.*
Example Documentation	• Methodology papers or documents demonstrating the method for attribution of patient services and/or episodes

3.2.f: Risk Adjustment	
Assessment	The QE provides a rationale for using or not using a risk adjustment method for each selected alternative measure. Furthermore, the QE provides a description of the risk adjustment method for each applicable measure. ***Note**: The QE is required to submit evidence only if it selects a measure that specifies a risk adjustment method.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure listed, the QE must include: a. The rationale for using or not using risk adjustment ***Note**: If risk adjustment was not used, the QE must include a detailed justification* b. The methodology used for risk adjustment (including case-mix or severity adjustment) wherever risk adjustment was applied
Example Documentation	• Methodology papers or documents demonstrating appropriate methods to employ risk adjustment
3.2.g: Outliers	
Assessment	The QE describes its outlier method (i.e., how to identify and account for outliers) for each selected alternative measure as applicable.
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure listed, the QE must include: a. The rationale for using or not using an outlier method ***Note**: If an outlier method was not used, the QE must include a detailed justification.* b. Where an outlier method was used, a detailed description of the outlier method, specifically how outliers were identified (e.g., more than three standard deviations from the mean) and how outliers were accounted for (e.g., truncation or removal of outlier)
Example Documentation	• Methodology papers or documents demonstrating the appropriate methods to handle outliers
3.2.h: Comparison Groups	
Assessment	The QE defines the comparison groups it uses to report results for each selected measure. ***Note**: The QE is required to submit evidence only if it plans to use comparison groups.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure to be included in QE performance reports, the QE must include: a. A description of the algorithm used to identify comparison groups (e.g., groups are compared by clinic for clinics with three or more practicing physicians) b. The geographic parameters that were used to compare providers to their peers (e.g., North region includes counties A, B, and C)
Example Documentation	• Methodology papers or documents demonstrating the comparison group methodology

3.2.i: Benchmarks	
Assessment	The QE defines the benchmarks it uses to report results for each selected measure. ***Note**: The QE is required to submit evidence only if it plans to use benchmarks.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook*. For each measure to be included in QE performance reports, the QE must include: a. How the benchmark was identified or estimated (e.g., benchmark from federal, state, or community report, calculated by averaging all the physician rates included in performance report) b. Type of benchmark used (e.g., national or regional 90th percentile, national or regional average)
Example Documentation	• Methodology papers or documents demonstrating the benchmark process
3.2.j: Rating Approaches	
Assessment	The QE uses valid methods for determining and calculating -ratings if measure calculations are aggregated or used to calculate provider ratings (e.g., stars, or good/ better/best). ***Note**: The QE is required to submit evidence only if it plans to report provider ratings.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure to be included in QE reports, the QE must include a detailed description of the rating approach(es), including rating calculation and statistical methods used. ***Note**: A screenshot from the public report that shows this information is not sufficient evidence for this item*.
Example Documentation	• Methodology papers or documents demonstrating the provider rating methodology
3.2.k: Prevalence Rates	
Assessment	The QE uses prevalence rates to show proportion of persons in a population who have a particular disease or attribute at a specified point in time or over a specified period. QEs can only use prevalence rates that include Medicare data if they are associated with an approved quality measure. ***Note**: The QE is required to submit evidence only if it plans to report prevalence rates.*
Evidence Requirement	1. Completed items in the *QECP Measure Information Workbook.* For each measure to be included in QE reports, the QE must include justification for how this prevalence rate is associated to the alternative measure.

Example Documentation	• Methodology papers or documents demonstrating the association with the quality measure
3.3: Provider and Public Report Design	
Assessment	The QE designs compliant provider and public reports using QE Medicare data and describes the plan for disseminating the reports to the public at least annually. ***Note**: The QE must report measures uniformly across the provider and public reports, including identical level of analysis, rates, ratings, peer group comparisons, and benchmarks. If a QE wishes to provide additional information to providers that it does not wish to provide to the public, it must adhere to the requirements described in Section 6.*
Evidence Requirement	1. Submit the confidential provider performance report and public report prototypes. In these reports, the type of information that the QECP team is looking for include: a. An understandable description of the measures used to evaluate the performance of providers so that consumers, providers, health plans, researchers, and other stakeholders can assess performance reports b. An understandable description of any provider rating approaches (e.g., stars or good/better/best) c. Attribution to the QE program for the source of the Medicare data. 2. A description of the process that will be used for making QE reports available to the public. 3. FOR QUASI QEs ONLY: Which reporting pathway does the quasi QE intend to engage in for their next QE public report? Note: QCDRs applying as quasi QEs that have not submitted measures to Care Compare are not eligible for Pathways 1 or 2. 4. FOR QUASI QEs ONLY: Have you submitted self-nominated measures or MIPS measures to Care Compare as a QCDR?
Example Documentation	• QE performance reports for providers • QE performance reports for the public • Screenshots • Document demonstrating dissemination of key methodology descriptions and results to providers and the public

3.6 Phase 3 Outcomes

There are two possible outcomes for Phase 3: *Compliant* and *Non-Compliant*.

3.6.1 Phase 3: Compliant

If the QE is found to be *compliant* with the Phase 3 requirements, it may distribute confidential reports to providers based on the approved provider performance report prototype. After allowing providers the requisite 60 days to review their confidential reports, the QE must proceed to public reporting using the approved public report prototype. If a QE is reporting at a regional level, and therefore not individually identifying providers or suppliers, then once deemed *compliant*, it must move directly to public reporting using the approved public report prototype.

3.6.2 Phase 3: Non-Compliant

If the QE is found to be *non-compliant* with the Phase 3 requirements, the QE will need to edit and resubmit their Phase 3 application. The QE will not be permitted to distribute confidential provider reports or release public reports until it is found to be fully compliant with the requirements. If the QE is unable to satisfy the minimum requirements, its QE certification status may be terminated.

SECTION 4. ONGOING PROGRAM ADMINISTRATION

To monitor QEs for potential violations and non-compliance with requirements per CFR § 401.719 *Monitoring and sanctioning of qualified entities*, the QECP contractor employs a systematic approach highlighted in Exhibit 6. Once an organization is approved as a QE, they are subject to OPA and monitoring. OPA monitoring consists of 1) QE self-reported changes, 2) QE Annual Report information and attestations, 3) QE application and public reporting submissions 4) triennial QECP Reapplication information and attestations, 5) QECP Compliance Monitoring Gray Literature Scans, and 6) QECP Data Security Audit. These activities are designed to ensure continued compliance with the QE program requirements.

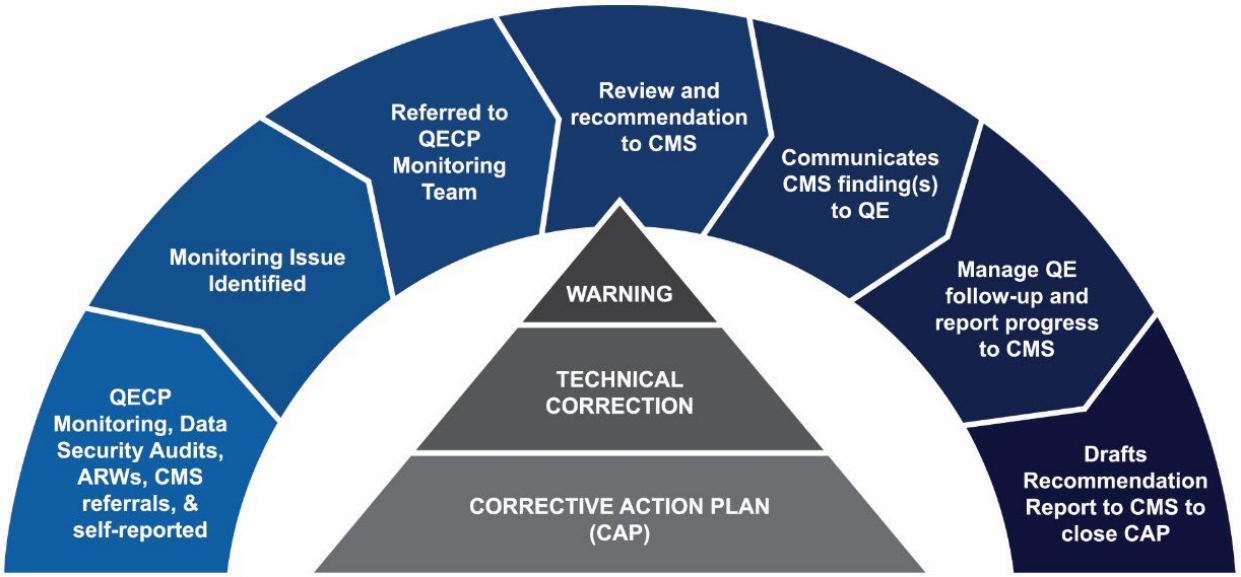

Exhibit 6: QECP Program Monitoring Framework

If a potential non-compliance issue is identified, it triggers a QECP monitoring review. A monitoring review may be conducted for any QE that is potentially out of compliance or at risk of non-compliance with program standards. During any monitoring review, if a program violation is determined by CMS, one of three monitoring actions: (1) Warning, (2) Technical Correction (TC), or (3) request for Corrective Action Plan (CAP) may result. A QE may receive any one of the monitoring actions as a starting point with the potential to move to a more elevated status should they not meet the terms of the initial action.

More information about OPA can be found on the Ongoing Program Administration page of the QECP website.

4.1 Reporting of Data Security Incidents

A QE is required to report any unauthorized access or disclosure of CMS information, suspected, or realized, to the QECP team and CMS immediately after the incident is discovered. According to the CMS DUA, the QE must report all breaches of data security pertaining to **personally identifiable information (PII)** to the CMS Action Desk within 1 hour, either by telephone at 410-786-2850 or by email at cms_it_service_desk@cms.hhs.gov. Note that reporting to the QECP team only satisfies the reporting requirement to CMS as it relates to the QECP. The QE is still obligated to report to other agencies, beneficiaries, covered entities, or CMS as required by contract or other applicable regulations, such as the **Health Insurance Portability and Accountability Act of 1996** (**HIPAA)** or state **data breach** laws.

The QECP team will investigate each incident as it is reported. Depending on the nature and severity of the incident, the QECP team may require a CAP to prevent further incidents and depending on the severity of the incident, it may trigger a virtual data security audit.

4.2 Reporting Changes after QE Certification

A QE may wish to modify its program operations, which were approved based on its application. Because changes to the QE's processes or systems may impact its ability to meet the minimum requirements established in the QECP, all such changes must be reported to the QECP team. This reporting procedure helps ensure that QEs are compliant with all requirements of the QECP at all times.

All entities deemed qualified as a result of the QECP application process have provided evidence in each of the following areas:

1. Entity (Element 1.1)
2. Financial Resources (Element 1.2)
3. Experience (Element 1.3)
4. Claims Data (Element 1.4)
5. Data Security (Element 2.1)
6. Provider Corrections and Appeals (Element 2.3)
7. Secure Transmission of Beneficiary Data (Element 2.4)
8. Measure Use & Methodology (Elements 3.1 and 3.2)
9. Provider and Public Report Design (Element 3.3)

The QE must notify the QECP team of all changes that relate to, or modify its compliance with, any of the minimum requirements evaluated during the application process.

4.2.1 When to Report a Change

Exhibit 6 provides guidance for the reporting procedures and relevant timeframes for all such changes but may not be inclusive of all reported change scenarios.

4.2.2 Procedure for Reporting Changes

The QE must report to the QECP team all changes to the approved operations plan according to the schedule described in Exhibit 6. The procedure to report such changes is based on updating the evidence the QE previously submitted to meet the minimum requirements during the application process. The procedure to report changes consists of the following steps:

1. The QE notifies its assigned PM of the intended change.
2. The QE works with the PM to identify which elements are modified by the change and the applicable evidence that should be provided.
3. In the QE online application, the QE provides a statement indicating the rationale for the proposed change and uploads all necessary documentation to demonstrate that the proposed change continues to meet the QECP minimum requirements.
4. The QECP team reviews and notifies the QE of approval or denial of the change via a Reported Change Decision Letter.

For data security reported changes, the process is slightly different. Before being able to determine what evidence a QE needs to submit to meet the requirements based on the proposed change, our data security review team will first need to review an updated data flow diagram with annotations. After the data security reviewer has assessed the updated diagram, your PM will communicate any additional evidence requirements to complete that change.

Exhibit 7: Reference Guide for Reporting Program Changes

Reporting Changes		
Reporting Change Requirement	**When To Report Change**	**Required/Example Supporting Documentation**
1.1: Entity		
The QE must report any termination or change in contractors, vendors, partners, subsidiaries or member organizations.	Immediately	**Required Documentation:** • An updated Letter of Commitment, including the Contractual Relationship Attestation (Appendix B) • Updated listing of contractors in General Information section of QECP online application
The QE must report changes in governance due to merger, acquisition, or consolidation (MAC).	Within 30 days following the MAC	**Required Documentation:** • Certificate of merger (if applicable) • Amended articles of incorporation
The QE must report changes to the official name of the organization(s).	Within 30 days following the name change	**Example Documentation:** • Amended articles of incorporation • Letter from the executive certifying that the name change will not affect any previously approved processes or explaining how the change will affect such processes.
The QE must report any change in its main point of contact for the QE program.	Immediately	**Required Documentation:** • Written notification to the QE's PM • Updated listing of contacts in General Information section of QECP online application
1.1: Entity (for quasi QEs only)		
A quasi QE must report any change in status as a CMS-approved QCDR.	Immediately	**Example Documentation:** • Written communication from CMS confirming change in status
1.2: Financial Resources		
The QE must report any changes to its business model that would affect its ability to cover the cost of the data and the cost of developing public reports.	Immediately	**Example Documentation:** • Written notification to the QE's PM ***Note**: Guidance will depend on the QE's current program phase.*

Reporting Change Requirement	When To Report Change	Required/Example Supporting Documentation
1.3: Experience		
If the QE leveraged the specific experience of a staff member, contractor, or collaborative to meet an experience requirement(s), and the staff member, contractor, or collaborative leaves, the entity must report the change.	Immediately	**Example Documentation:** • Written notification to the QE's PM • Updated evidence to demonstrate the entity still meets the minimum experience requirements
1.4: Claims Data		
The QE must report any decrease in the amount of claims data from non-Medicare sources being used to qualify for the QE program.	Immediately	**Required Documentation:** • Updated QECP Data Source Attestation • Evidence that remaining data are sufficient to address methodological concerns regarding sample size and reliability
The QE must report any changes to the geographic area (region, state, county) for which public reporting will incorporate QE Medicare data.	Immediately if the change is associated with a change in other-payer claims data; otherwise, within 30 days	**Required Documentation:** • Updated QECP Data Source Attestation that reflects the new coverage area and demonstrates that the QE has sufficient other-payer claims data for the new region/state/county
1.1: Entity & 2.1: Data Security		
The QE must report any changes to the data analytics/warehousing vendors or contract changes related to the organizations/vendors handling QE Medicare data or QE Medicare data security.	Immediately	**Example Documentation:** • Updated Phase 2 evidence, including a new QECP Data Security Review and Data Flow Diagram • New Letter of Commitment detailing role of new contractor or vendor, as applicable

Reporting Change Requirement	When To Report Change	Required/Example Supporting Documentation
2.1: Data Security		
The QE must report any significant changes to the data security and privacy policies or procedures that it had in place during the application process. A significant change in Data Security is defined as an action that is likely to affect the security state of an information system or its environment of operation. *Examples of significant changes include, but are not limited to, changes to:* Data hosting provider Internet service providers used to transmit QE Medicare data Physical locations where QE Medicare data are stored, processed, accessed, or transmitted (e.g., building moves) Staff with primary responsibility for data security.	Immediately	**Example Documentation:** • Updated QECP Data Security Review, with revised supporting documentation • Updated data flow diagram ***Note:*** *A QE may not, under any circumstances, use a measure, create a report, or issue a report until the QECP team receives notification of the change, reviews it, and informs the QE of the review outcome.*
The QE must report any unauthorized access or disclosure of CMS data, suspected, or realized, to the QECP team and CMS.	Immediately after the incident is discovered	**Example Documentation:** • Breaches of data security that pertain to PII must be reported to the CMS Action Desk within 1 hour via telephone at 410-786-2850 or email at CMS_it_service_desk@cms.hhs.gov. • QEs should work with their PM to identify appropriate documentation depending on the nature of the breach. However, at a minimum, copies of incident notifications and reports will generally be required.
The QE must report all violations of the CMS DUA by the entity or its contractors. Examples include unauthorized data reuse, physically moving the QE Medicare data without CMS approval, and violating cell size suppression policy.	Immediately	**Example Documentation:** • QEs should work with their PM to identify appropriate documentation depending on the nature of the violation. However, at a minimum, copies of incident notifications and incident reports will generally be required.

Reporting Change Requirement	When To Report Change	Required/Example Supporting Documentation
2.3: Provider Corrections and Appeals & 2.4: Secure Transmission of Beneficiary Data		
The QE must report any changes to its confidential provider corrections and appeals process related to the privacy and security protections for the release of beneficiary identifiers or claims data to providers	Immediately	**Example Documentation:** • Updated process documents • Updated data flow diagram with annotations
The QE must report any changes to the level of analysis for QE public reports (regional or provider-identified).	Immediately	**Required Documentation:** • If changing from regional to provider-identified level of analysis, the QE must provide evidence of experience with Corrections and Appeals (Element 1.3) and all required documentation for Elements 2.3 and 2.4 • If changing from provider-identified to regional level of analysis, the QE must provide evidence under Element 2.3 explaining how providers cannot be re-identified in QE's public reports
3.1: Standard Measure Use & 3.2: Alternative Measure Use		
The QE must report if it begins using risk adjustment methods or makes changes to risk adjustment methods for each applicable performance measure.	At least 90 days before the intended release of confidential performance reports to providers	**Example Documentation:** • For standard measures, completed items for Element 3.1.d in the *QECP Measure Information Workbook* • For alternative measures, completed items for Element 3.2.f in the *QECP Measure Information Workbook*, including methodology papers or documents demonstrating that the proposed methods are appropriate.
The QE must report changes to approved standard and alternative measure specifications. This includes changes in the eligible population, denominator, numerator, exclusions, measured time periods, specified data sources, and risk adjustment method.	At least 60 days before the intended release of confidential performance reports to providers	**Example Documentation:** • For standard measures, completed items for Element 3.1.a in the *QECP Measure Information Workbook* • For alternative measures, completed items for element 3.2.a in the *QECP Measure Information Workbook*, including updated measure specifications
The QE must report any new standard measure it wishes to add to its approved list of measures.	At least 30 days (60 days is encouraged) before the intended release of confidential performance reports to providers	**Example Documentation:** • An explanation of the standard measure that will be added in the next public reporting cycle • Revised QECP Measure Information Workbook that includes the added measure • Applicable evidence for Elements 3.1.a-3.1.h

The QE must report any new alternative measure it wishes to add to its approved list of measures.	At least 90 days before the intended release of confidential performance reports to providers or at least 30 days before the intended release of regional public reports.	**Example Documentation:** • An explanation of the alternative measure that will be added in the next public reporting cycle • Revised *QECP Measure Information Workbook* that includes the added measure • Applicable evidence for Elements 3.2.a–3.2.k (i.e., measure specification)

Reporting Change Requirement	When To Report Change	Required/Example Supporting Documentation
The QE is required to monitor the release of standard measures (e.g., measures newly endorsed by NQF) and notify the QECP team of any newly released standard measure that is similar to one of its QECP-approved alternative measures. The QE must inform the QECP team whether it intends to switch to the standard measure or not.	The QE must switch to the standard measure within 6 months of the date that the standard measure becomes available or provide a justification for not switching.	**Example Documentation:** • *If the QE switches to the standard measure:* ○ An explanation of the standard measure that will be added in the next public reporting cycle ○ Revised QECP Measure Information Workbook that includes the added measure ○ Applicable evidence for Elements 3.1.a-3.1.h • *If the QE does not switch to the standard measure:* ○ Written justification for continuing to use the alternative measure
The QE is required to monitor the endorsement status of its QECP-approved standard measures and notify the QECP team if any standard measure loses endorsement status and therefore becomes an alternative measure. If the QE wishes to continue to publicly report the measure, but as a new alternative measure, within 6 months of the date that the measure loses endorsement status, the QE must submit evidence for Element 3.2. The QECP team will have 60 days to reach a decision on approval or disapproval of the alternative measure.	Within 6 months following the date that the measure loses endorsement status	**Example Documentation:** • *If the QE wants to publicly report the measure as alternative:* ○ Revised *QECP Measure Information Workbook* that includes the added alternative measure with all completed information and evidence for Elements 3.2.a–3.2.h • *If the QE no longer wishes to publicly report the measure:* ○ An explanation that the measure will not be included in the next public reporting cycle
3.3: Provider and Public Report Design		
The QE must report any significant changes to the appearance or content of Phase 3-approved confidential provider performance reports or public reports. *Significant changes include changes to:* Provider ratings approach Level of analysis for reported measures Comparative reporting by product line QE's public report website address	For either a change in the provider or public report, at least 30 days (60 days encouraged) before the intended release of confidential performance reports to providers	**Example Documentation:** • Explanation of the changes • Revised provider and/or public report prototype or screenshots

Reporting Change Requirement	When To Report Change	Required/Example Supporting Documentation
The QE must report any changes in the dissemination plan for sharing reports with the public, including the public report release timeline and frequency.	At least 30 days (60 days is encouraged) before the intended release of confidential performance reports to providers	**Example Documentation:** • Explanation of the changes • New dissemination plan that includes the timeline and frequency of public reports
3.1–3.3: Measure Use & Reporting (for quasi QEs only)		
A quasi QE must notify the QECP team if it was previously exempt from submitting evidence for Phase 3 and wishes to add measures to its public reports that were not included in the QCDR self-nomination process.	At least 120 days before its intended confidential performance report release to providers	**Required Documentation:** • All relevant documentation for these new measures for Elements 3.1–3.3

4.3 QE Annual Reports

As defined in the **QE regulations** (42 CFR § 401.719), QEs are required to provide annual reports containing information related to program adherence to allow the QECP team to continually monitor and assess their performance in the program. QEs must submit an annual report for each calendar year, with the exception of QEs certified after November 1 of that year. In other words, QEs certified on or after November 1 of a given year will *not* be required to submit an annual report for that year. The QECP team will provide instructions to QEs each year on the timeline for completing and submitting their **annual report**. As part of OPA, the QECP team will review these reports and follow up with QEs, as necessary.

To make these reports as comprehensive as possible, QE regulations require the following elements in each annual report:[10]

- *The volume of Medicare and other-payer claims combined.* QEs must report how much non-Medicare claims data they have available to combine with the QE Medicare data received from CMS for use in their standard and alternative performance measures. Please note that QCDRs are required to provide information about the changes in their total provider enrollment and whether there was a net increase or decrease in total provider counts.
- *The percent of the overall market share the number of claims represent in the QE's geographic area.* When QEs determine the number of non-Medicare and Medicare claims they were able to combine, they must determine and report the percentage of the market share of their geographic region these claims represent.
- *The number of measures calculated.* QEs must report the number of standard and alternative measures in which QE Medicare data were included and reported publicly in the past year, as well as any measures that they may have added or deleted through the OPA process for reporting changes. This includes any measures released through a supplemental report.
- *A measure of public use of the reports.* QEs are expected to ensure that their public reports are reaching the target audiences and that consumers are using the data contained in these reports. QEs must collect and report some measure of public use of their reports (e.g., website hits, examples of consumer use of measure results). This includes any activity from supplemental public reports.
- *The number of providers and suppliers requesting claims data through the corrections and appeals process.* Accurate reporting on providers is a crucial element of the QECP. QEs must report the number of providers requesting claims data through the corrections and appeals process as an indication of how reports are being received by medical professionals.
- *The number of requests for claims data fulfilled.* QEs must report the number of provider requests fulfilled, including the number of claims sent to each provider.
- *The number of error corrections.* Accurate reporting should be a key focus for QEs. QEs must report the number of corrections made to the provider performance reports as a direct result of the corrections and appeals process and of any other process in which errors were detected and reported to the QE.

[10] QE regulations, 42 CFR §401.719(b). Depending on a QE or quasi QE's progress through the phased application process, it may not be required to respond to all annual report elements. Annually, the QECP team will provide specific annual report instructions to each QE and quasi QE.

- *The types of problems leading to requests for error correction.* QEs must also report what kinds of errors were identified, both those that upon investigation did not require correction and those that did require correction (e.g., system issues, missing data feeds, or misattribution of patient services and episodes).
- *The amount of time to acknowledge requests for error correction.* Once a request for error correction is received from a provider, QEs must acknowledge receipt before processing the request. QEs must report the time it took to acknowledge each provider request for correction or appeal.
- *The amount of time to respond to requests for error correction.* QEs should respond to provider requests for error corrections in a timely manner. QEs must report the amount of time it took to respond to each provider request for error correction.
- *The number of requests for error correction resolved.* QEs must report how many errors were corrected and how many identified errors were not corrected. This must be accompanied by a description of how these errors were resolved or the reason for no resolution.
- *The security and privacy of QE Medicare data*. Security and privacy are essential to the QECP, in addition to the information required by QE regulations, all QEs are required to include in their QECP annual report summary of incidents involving unauthorized access or disclosure of CMS information, suspected or realized, over the past year. QEs must include the date(s), type(s), and resolution of all incidents. This summary is in addition to the required immediate notification QEs must provide to the QECP each time a data security incident occurs
- *Non-Public Analyses and Data.* QEs that choose to engage in **additional uses of QE Medicare data**, including providing QE Medicare data at no cost, or providing or selling non-public analyses, must provide descriptive information related to each analysis bought or sold and each occurrence of QE data provided or sold (e.g., authorized user, total fees received, topic or purposes of the analysis).
- *QE feedback.* This step is optional however, we encourage QEs to complete a survey for the annual report to provide feedback related to the application process, technical assistance, communication with the QECP team, or any other areas.

4.3.1 Procedure for Submitting Annual Reports

QEs have access to their *Annual Report* through the QECP online application. If a QE has not received QE Medicare data or released a QE public report by the report deadline, it will submit several tables in the workbook as "not applicable." Once the annual report has been submitted, QEs should inform their PM. The annual reports will then be reviewed and either assessed as "Compliant" or referred to the Monitoring team for review.

More information on submitting Annual Reports can also be found in the Annual Report Webinar on the QECP website under QE Program Information --> Ongoing Program Administration --> Webinars. This webinar is offered to QEs each year to provide a demonstration of the annual report process. For more information, please contact your PM.

4.4 Monitoring Reviews

A **monitoring review** may be conducted for any QE that is potentially out of compliance or at risk of non-compliance with program requirements. The review may occur at any time after the QE has obtained QE Medicare data. An assessment of compliance may occur during phase application submission, periodic

environmental scans of QE activities, in the course of a reported change or annual report submission, or as part of the release of public or non-public reports.

During the monitoring review, the QECP team assesses a QE's compliance with the requirements related to data security and privacy, the provider corrections and appeals process, and performance measures and public reporting. In certain cases, a monitoring review may consist of a virtual data security audit. As referenced in the QE regulations (42 CFR § 401.719), a data security audit may result in a request to the QE for updated documentation to resolve the issue of non-compliance.

Monitoring reviews may result in one of three outcomes: a Warning, a TC, or a CAP Request.

4.4.1 Warning

A warning is the lowest level of response by the QECP team to probable or potential violations. The QE will receive a letter, signed by the QECP Project Director, outlining the concern, and explaining how to avoid it in the future. No evidence submission will be required of the QE.

4.4.2 Technical Correction

A Technical Correction (TC) request is issued by CMS to correct a compliance issue with a QE's performance under the QECP. A CAP Request describes the compliance issue, outlines the steps the QE needs to take to come back into compliance, and sets a timeline by which the QE must address the issue. The QE will receive a letter from CMS that explicitly outlines the non-compliant behavior and the actions required of the QE to return to compliance. Evidence submission will be required and will be reviewed by the appropriate subject matter experts to assess compliance.

4.4.3 Corrective Action Plan

CAPs are imposed as a result of the highest level of violation and require a remediation plan. The QE will receive a CAP Request from CMS explicitly outlining the QE's program violations, and the requirement to develop a 30-, 60-, or 90-day CAP. Both a remediation plan and evidence of remediation are required and will be reviewed by the relevant SMEs. The QECP team will send a recommendation report and a CAP decision letter to CMS for final approval.

Once CMS has approved the CAP, the QECP team will monitor the QE to ensure that it adheres to all aspects of the CAP. This monitoring may include checking to ensure that the QE is adhering to the CAP timeline and meeting deliverable schedules. If the QECP team finds that a QE is not following the CAP, the team may step in and take more immediate action.

4.5 OPA Outcomes

The review and assessment of OPA activities, including reporting data security breaches, reporting changes, submitting annual reports, and the monitoring reviews will result in one of three outcomes: *OPA Compliant, In Danger of OPA Non-Compliance*, and *OPA Non-Compliant*.

4.5.1 OPA Compliant

If the QECP determines that the QE is in good standing, the QE will be deemed *OPA compliant*, and no further action will be taken.

4.5.2 In Danger of OPA Non-Compliance

If the QE is found to be generally compliant but requires further review or modification of certain OPA components to be in full compliance, it will receive notification that it is *in danger of OPA non-compliance*.

Depending on the level of non-compliance, the QE may require a CAP or may be permitted to continue working with QE Medicare data under observation by the QECP team.

4.5.3 OPA Non-Compliant

If the review of any of the OPA components uncovers a critical deficiency, the QE will receive notification that it is *OPA non-compliant*. An outcome of OPA non-compliance means that the QE must immediately stop calculating and reporting on performance measures that include QE Medicare data. Depending on the degree of non-compliance, the QE may be able to undergo a CAP in order to resume reporting, or CMS may terminate the QE's certification status and require the QE to return or destroy all QE Medicare data, as specified in the CMS DUA.

SECTION 5. REAPPLICATION

QE certification is valid for 3 years. QEs must reapply for certification 6 months prior to the end of their certification period to remain in good standing. This 6-month anniversary is considered the reapplication deadline by the QE program. QEs continue to be in good standing until their **reapplication** is either approved or denied.

QEs will receive a reapplication notification from their PM 3 months prior to their reapplication deadline and will be asked whether they intend to reapply. QEs may request data until their certification period ends. If a QE reapplies and its geographic region changes during the reapplication process, the QE will be required to return or destroy any data that it is ineligible to keep at the end of the 3-year certification period. QEs that do not intend to reapply may request data until their QE certification expires, however, they will be required to return or destroy any data at the end of the 3-year certification period. For more information about reapplication, please see the Reapplication page of the QECP website.

5.1 QE Reapplication Policy

The reapplication process takes significantly less time and effort than the initial phased application process. The reapplication process leverages QE documentation already on file with CMS and requires QEs to respond to a form pre-populated with information by their PM and consists of no more than 10 statements based on where a QE is in the application process at the time of Reapplication. These statements are summarized in Section 5.2. During reapplication, QEs must report changes to previously assessed QECP elements and submit supporting documentation to confirm such changes.

Reapplication can take up to 3 months for the QE to complete and submit. The Reapplication review, including CMS' final outcome decision, is estimated to take up to 15 business days from the submission of a complete and validated Reapplication that meets all requirements.

5.2 QE Reapplication Program Requirements

QEs are responsible for completing the reapplication form and submitting supporting documentation as needed. QEs will work with their PM to determine which statements will be required of them based on their status in the program. The QE will then upload all documentation to the online application. The detailed evidence requirements for reapplication are shown in Exhibit 7.

5.3 Quasi QE Reapplication Program Requirements

Reapplication will be used to verify the selected QQE pathway for public reporting. As such, Statements 7, 8, and 9 will vary slightly in language for QQEs and will reference the most recently submitted evidence on measure selection (e.g., self-nominated, standard, or alternative), reporting platform (e.g., Care Compare) pathway. QQEs will be asked to describe any changes to the number of providers in their

registry for Statement 2. Quasi QEs should reach out to their PMs for any quasi-QE specific Reapplication questions.

Exhibit 8: QECP Minimum Requirements Review: Reapplication QE Program Requirements

Reapplication	
QE Program Requirement	**Element**
1.1: Identify changes to the QE's organization	
Assessment	**Statement 1**: Your organization intends to continue to contract with the same organization(s) to fulfill the QECP requirements. ***Note**: Public and non-public reports that include QE Medicare data must not be disseminated using a new data analytics/warehousing vendor prior to the new vendor (and lead QE) submitting updated QECP Phase 2 evidence and obtaining CMS approval (see Section 4.2).*
Evidence Requirement (if applicable)	1. If your organization plans to work with new/additional contractors, vendors, partners, subsidiaries or member organizations, complete the QECP Letter of Commitment, including Appendix B: Contractual Relationship Attestation, which includes an attestation to breach of contract liability between parties, with potential to collect damages for failure to perform.
1.4: Identify changes to the QE's ability to obtain claims data from at least one other source to combine with the QE Medicare data	
Assessment	**Statement 2**: Your organization still receives the same sources and amounts of other-payer claims data for the approved geographic areas in the pre-filled text box below ***Note**: A QE may not, under any circumstances, use a measure, create a report, or issue a report after the amount of claims data from other sources available to the QE decreases until the QECP team determines either (1) that the remaining claims data are sufficient or (2) that the QE has collected adequate additional data to address any identified deficiencies (see Section 4.2).*
Evidence Requirement (if applicable)	1. If the geographic area has changed, submit a new *QECP Data Source Attestation.* 2. If the amount of other-payer claims data received by your organization has *increased*, submit a new *QECP Data Source Attestation.* If the amount of other-payer claims data received by your organization has *decreased*, submit a new *QECP Data Source Attestation*. In addition, provide an explanation, by data supplier name, of the reason why the data source is no longer available to your organization, or the reason why the amount of data received by the supplier has decreased. Submit documentation that demonstrates that the remaining claims data from other sources are sufficient to address methodological concerns regarding sample size and reliability.
2.1: Identify changes to the QE's data security and privacy policies and procedures	

Assessment	**Statement 3**: The data flow diagram submitted by your organization still accurately demonstrates (1) how sites that access the QE Medicare data are connected, and (2) how QE Medicare data flow through your organization from receipt to public reporting (including the confidential provider corrections and appeals process) **Statement 4**: Since Phase 2 approval, or submission of your organization's most recent QECP annual report, your organization has made significant changes to the data security environment and practices A significant change is defined as an action that is likely to affect the security state of an information system or its environment of operation. Some examples include, but are not limited to: • Modifications to cryptographic modules or services; • Modifications to security controls; • Moving to a new facility; • Change in vendors, business partners, or service providers; • Changes in data hosting providers; • Changes in staff with primary responsibility for data security; • Data breaches and other violations of the CMS DUA; • Acquiring specific and credible threat information that the organization is being targeted by a threat source; or • Establishing new/modified laws, directives, policies, or regulations. If there is any uncertainty about whether a change in a data security program is significant and should therefore be reported, please consult with the QECP team (support@QEMedicaredata.org) to determine the appropriate next steps.
Evidence Requirement (if applicable)	1. If your organization has experienced a change to its security environment through which QE Medicare data flows, submit an updated, annotated QE data flow diagram. 2. If your organization has experienced a change to its data security environment or practices, provide an explanation of the changes, including the date when each change occurred.
2.3 & 2.4: Identify changes to the corrections and appeals process; identify any changes related to the secure transmission of beneficiary data	
Assessment	**Statement 5:** Your organization would like to change their level of reporting (provider-identified vs regional) prior to the next reporting cycle for either public or non-public reports. **Statement 6**: Your organization would like to make a change to their corrections and appeals process prior to the next reporting cycle. This includes any changes to your organization's privacy and security protections for the release of beneficiary identifiers and/or claims data to providers.
Evidence Requirement (if applicable)	1. If your organization would like to report publicly or non-publicly at the provider level and had previously reported at a regional level, please provide a corrections and appeals process including the process that would allow an entity to securely transmit beneficiary claims to providers.

	2. If your organization would like to report publicly or non-publicly at the regional level and had previously reported at a provider level, please provide an explanation of the masking methodology that would prevent providers from being re-identified. 3. If your organization is planning to make changes to the confidential provider corrections and appeals process, provide an explanation describing the changes. These changes must be reflected in the QE data flow diagram provided under Statement 3. Changes related to contractual relationships with data analytics/warehousing vendors are subject to the requirements of Statements 1and 3.
3.1: Identify changes to the standard measures the QE intends to report in its next public reporting cycle	
Assessment	**Statement 7**: Your organization intends to continue reporting the same *standard* measures in its next public reporting cycle. ***Note**: QEs are required to notify the QECP team of any new standard measures they wish to add to their approved list of measures at least 30 days before the intended confidential performance release to providers for the corrections and appeal process (see Section 4.2).*
Evidence Requirement (if applicable)	1. If your organization would like to change the *standard* measures that have previously been publicly reported, provide an explanation of the standard measures that will be added or removed in your organization's next public reporting cycle. For measures that will be added, submit a revised *QECP Measure Information Workbook*, accompanied by the required supporting documentation for Element 3.1.
3.2: Identify changes to alternative measures the QE intends to report in its next public reporting cycle	
Assessment	**Statement 8**: Your organization intends to continue reporting the same *alternative* measures in its next public reporting cycle. ***Note**: QEs are required to notify the QECP team of any alternative measures they wish to add to their approved list of measures. QEs must notify the QECP team of any new alternative measures at least 60 days before the intended confidential performance report release to providers (see Section 4.2) and are strongly encouraged to notify the team up to 90 days beforehand.*
Evidence Requirement (if applicable)	1. If your organization would like to change the *alternative* measures that have previously been publicly reported, provide an explanation of the alternative measures that will be added or removed in your organization's next public reporting cycle. For measures that will be added, submit a revised *QECP Measure Information Workbook*, accompanied by the required supporting documentation for Element 3.2.
3.3: Identify changes in the design of reports for providers and the public	
Assessments	**Statement 9**: Your organization would like to change the content or appearance of its provider or public report during its next reporting cycle. A "change" is defined as a significant modification in the provider ratings approach, level of analysis for reported measures, comparative reporting by product line, or website address, for example, but excludes changes due to the addition or removal of performance measures. ***Note**: QEs must notify the QECP team of changes to the provider and/or public prototype report and submit to the QECP team the new prototype report(s) at least 30 days before the intended confidential release to providers (see Section 4.2).* **Statement 10**: Your organization would like to change its dissemination plan for informing intended audiences of the issuance of its QE performance reports. This includes anticipated changes to the public report release schedule and frequency.

	***Note**: QEs must notify the QECP team of changes in the dissemination plan for sharing reports with the public and submit the new plan at least 30 days before the intended confidential performance report release to providers (see Section 4.2).*
Evidence Requirement (if applicable)	1. If your organization would like to make changes to the content or appearance of provider and/or public reports, provide an explanation of the changes, and submit the revised provider and/or public report prototype. 2. If your organization would like to make changes to the dissemination plan, provide an explanation of the changes.

5.3 Reapplication Outcomes

After the reapplication review, a certification decision is rendered. CMS will assign the QE an outcome of *Qualified* or *Not Qualified*.

5.3.1 Reapplication: Qualified

A QE that has reapplied to the QECP receives the status *Qualified* if it demonstrates complete compliance with the reapplication requirements. This status is valid for 3 years from the date of notification of CMS approval unless the QE's status is otherwise terminated (see Section 5.4).

After recertification, QEs in Phase 2 or 3 must continue to work toward projected submission dates for their Phase 2 or Phase 3 evidence. QEs must work with ResDAC and CMS to submit QE Medicare data requests and pay associated fees to receive annual and quarterly updates of QE Medicare data.

5.3.2 Reapplication: Not Qualified

A QE that has reapplied to the QECP receives the status *Not Qualified* if it has not demonstrated complete compliance with the reapplication requirements. A failure on any requirement will result in an outcome of *Not Qualified*. A QE that receives a reapplication outcome of *Not Qualified* may not submit a second reapplication, must cease public reporting initiatives using QE Medicare data, and must return or destroy QE Medicare data.

QEs that receive the status *Not Qualified* may apply for *Phase 1 QE certification* no sooner than 90 business days after the date of the reapplication decision letter from CMS.

5.4 Maintaining and Losing Certification Status

5.4.1 Expiration and Renewal

QE certification is valid for 3 years from the date of notification of CMS approval. The QE may submit data requests and pay associated fees to receive updates of QE Medicare data until the end of its certification period. At that time, the QE must have successfully reapplied to the QECP and have been approved to continue receiving data. If a reapplication is not submitted or approved, the QE must destroy the data.

5.4.2 Termination

During any phase of the minimum requirements review or the monitoring review (if applicable), a QE may have its certification terminated if it is no longer compliant with program requirements.

5.4.3 Reconsideration

As stated in the QE regulations (42 CFR § 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.

5.4.4 Voluntary Forfeiture

The QE regulations (42 CFR § 401.721) note that QEs may voluntarily terminate their agreement with CMS once they have entered the minimum requirements review, a monitoring review, or the OPA 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 QE Medicare data that it received under the program. Fees paid to CMS by the QE will not be refunded.

SECTION 6. ADDITIONAL USES OF QE MEDICARE DATA

Once a QE passes the Phase 2 Data Security review and obtains data, it may engage in additional non-public uses of QE Medicare data, beyond the public reporting requirement. Any QE that elects to engage in additional uses of QE Medicare data under the QE program must comply with all QECP requirements described in this Program Guide, including, but not limited to, the QECP phased minimum requirements review and public reporting.

For more information, please see the Use of Medicare Data page of the QECP website.

6.1 Providing or Selling De-identified Non-Public Analyses

QEs may use **combined data** to create de-identified[11] non-public analyses and provide or sell these de-identified analyses to **authorized users**. The requirement to use combined data does not prevent QEs from providing or selling analyses that allow the authorized user to drill down by payer type to Medicare only- results. For example, a QE may provide or sell a provider report that includes the provider's overall score on certain quality and resource use measures (using combined data) and then presents scores for each of these measures by payer type (including a Medicare FFS category).

A QE must enter into a contractually binding non-public analyses agreement with the authorized user as a precondition of providing or selling de-identified analyses. More on this topic is covered in Section 6.4.2: The Non-Public Analyses Agreement, which also discusses permissible uses of de-identified non-public analyses).

6.1.1 Authorized Users of De-identified Non-Public Analyses

A QE may provide or sell de-identified non-public analyses to the following authorized users (including any contractors or business associates described in the definition of authorized user): (1) a provider; (2) a supplier; (3) an **employer**; (4) a **health insurance issuer**; (5) a **medical society**; (6) a **hospital association**; (7) a **health care provider and/or supplier association**; (8) a **state entity**; and (9) a federal agency.

A QE may only provide or sell a non-public analysis to a health insurance issuer after the health insurance issuer or a business associate of that health insurance issuer has provided the QE with claims data that represent a majority of the health insurance issuer's covered lives, using one of the four methods of calculating covered lives established at 26 CFR § 46.4375-1(c)(2), for the time period and geographic region covered by the issuer requested- non-public analysis. A QE may not provide or sell a non-public analysis to a health insurance issuer if the issuer does not have any covered lives in the geographic region covered by the issuer-requested non-public analysis.

If the authorized user is an employer, the authorized user may only use the analysis or derivative data for purposes of providing health insurance to employees, covered dependents of employees, or covered retirees of that employer.

[11] Regardless of the HIPAA covered entity or business associate status of the QE and/or the authorized user, de-identification must be determined based on the standards for HIPAA covered entities found at 45 CFR § 164.514(b). More information on the HIPAA de-identification standards can be found on the Health and Human Services (HHS) Office for Civil Rights website at http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

6.1.2 Corrections and Appeals for Non-Public Analyses

Non-public analyses that contain information that individually identifies a provider or supplier (regardless of the level of the provider or supplier, that is, an individual clinician, a group of clinicians, or an integrated delivery system) may not be disclosed unless one of the following three conditions apply:

- The analysis only individually identifies the provider or supplier receiving the analysis.
- Every provider or supplier individually identified in the analysis has been afforded the opportunity to appeal or correct errors using the process described below.
- Every provider or supplier individually identified in the analysis has notified the QE, in writing, that analyses may be disclosed to the authorized user without first going through the corrections and appeals process.

A QE must comply with the following before disclosing non-public analyses which contain information that individually identifies a provider or supplier:

- At least 65 calendar days before disclosing the analyses, a QE must confidentially notify a provider or supplier that non-public analyses that individually identify the provider or supplier will be released to an authorized user. This confidential notification must include a short summary of the analyses (including the measures calculated), the process for the provider or supplier to request the analyses, the authorized user receiving the analyses, and the date on which the QE will release the analyses to the authorized user.
- A QE must allow providers and suppliers the opportunity to opt into the review and correction process at any time during the 65-calendar-day period. If a provider or supplier chooses to opt-in to the review and correction process more than 5 days into the notification period, the time for the review and correction process is shortened from 60 days to the number of days between the provider or supplier opt-in date and the release date specified in the confidential notification.

6.2 Providing or Selling Patient De-Identified Data

A QE may provide or sell de-identified[12] combined data or provide QE Medicare-only data at no cost to certain authorized users. For combined data, there is no specific minimum threshold for the amount of other-payer claims data that must be combined with the QE Medicare data. QEs are permitted to determine an appropriate fee to charge authorized users for access to the combined data.

A QE must enter into a contractually binding **Qualified Entity Data Use Agreement (QE DUA)** with an authorized user prior to providing or selling any de-identified data. More information on this topic may be found in Section 6.4.1: The QE DUA, which also discusses permissible uses of de-identified data.

6.2.1 Authorized Users of Patient De-identified Data

QEs are permitted to provide (or sell, where applicable) de-identified data only to the following authorized users (including any contractors or business associates described in the definition of authorized user): (1) **providers of services**, (2) suppliers, (3) medical societies, and (4) hospital associations.

[12] Regardless of the HIPAA covered entity or business associate status of the QE and/or the authorized user, de-identification must be determined based on the standards for HIPAA covered entities found at 45 CFR 164.514(b). Additional information on the HIPAA de-identification standards can be found on the HHS Office for Civil Rights website at: http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

6.3 Providing or Selling Patient-Identifiable Data and Analyses

QEs may provide or sell **patient-identifiable** combined data,[13] or provide patient-identifiable Medicare-only data at no cost, to certain authorized users. QEs may also use combined data to create patient-identifiable non-public analyses and provide or sell these identifiable analyses to authorized users. The requirement to use combined data to create the analyses does not prevent QEs from providing or selling identifiable analyses that allow the authorized user to drill down by payer type to Medicare only- results. For example, a QE may provide or sell a provider a report that includes the provider's overall score on certain quality and resource use measures (using combined data) and then present scores for each of those measures by payer type (including a Medicare FFS category).

A QE is required to enter into a QE DUA with any authorized user as a precondition of providing or selling non-public analyses that contain patient-identifiable information or data. More on this topic is covered in Section 6.4.1: The QE DUA, which also discusses permissible uses of identifiable data and analyses.

6.3.1 Authorized Users of Patient-Identifiable Data and Analyses

If consistent with all applicable laws, data or analyses that individually identify a beneficiary may only be disclosed to a provider or supplier with whom the identifiable individual in such data or analyses has a **patient** relationship. "Patient" is defined as an individual who has visited a provider or supplier for a face-to-face or telehealth appointment at least once in the past 24 months.

6.3.2 Corrections and Appeals for Non-Public Analyses

Patient-identifiable non-public analyses also require a provider corrections and appeals process. For more information on the corrections and appeals requirements for non-public analyses, see Section 6.1.2.

6.4 Contractually Binding Agreements

There are three different contractual agreements in the QE program. The first contractual agreement is the CMS DUA between CMS and the QE. The CMS DUA must be in place prior to the QE receiving Medicare data. It contains all of the data use requirements that the QE and any Phase 2-approved contractor must comply with to participate in the QE program. For more information on the CMS DUA, see Section 2.6.

The second agreement is the QE DUA. The QE DUA is executed between a QE and an authorized user and is a precondition of selling or disclosing any combined data or Medicare claims data or non-public analyses that includes individually identifiable beneficiary data. The QE DUA contains all of the provisions that the authorized user must comply with to receive and maintain the QE data or patient-identifiable analyses. More information on the QE DUA is provided in Section 6.4.1.

The third agreement is the non-public analyses agreement between a QE and an authorized user and is a precondition of providing or selling beneficiary de-identified analyses. The non-public analyses agreement contains all of the provisions that the authorized user must comply with to receive and maintain the de-identified analyses (see Section 6.4.2).

[13] Regardless of the HIPAA covered entity or business associate status of the QE and/or the authorized user, de-identification must be determined based on the standards for HIPAA covered entities found at 45 CFR 164.514(b). Additional information on the HIPAA de-identification standards can be found on the HHS Office for Civil Rights website at http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

6.4.1 The QE DUA

As a precondition of providing or selling any QE data (including combined, Medicare-only, beneficiary-identifiable, or de-identified data) or providing or selling non-public analyses containing **protected health information (PHI)**, the QE must enter into a QE DUA with the authorized user.[14] The QE DUA must contractually bind the authorized user (including any contractors or business associates described in the definition of authorized user) to the following:

- Permissible uses;
- Privacy and security requirements; and
- The requirement to notify the QE of any violations of the QE DUA, to cooperate in the QE's efforts to mitigate any harm that may result from such violations, and to comply with the breach provisions governing QEs.

Providing or selling beneficiary de-identified non-public analyses is governed not by the QE DUA, but rather by the non-public analyses agreement.

Permissible Uses Under the QE DUA

The QE DUA must contractually bind the authorized user to the following permissible uses of data or analyses that the authorized user receives under the QE DUA. Under a QE DUA, the authorized user may use the QE data and the non-public analyses containing PHI only in a manner similar to that of a HIPAA covered entity under the following provisions:

- Activities falling under paragraph (1) of the definition of "health care operations" under 45 CFR § 164.501: Quality improvement activities, including care coordination activities and efforts to track and manage medical costs; patient-safety activities; population-based activities such as those aimed at improving patient safety, quality of care, or population health, including the development of new models of care, the development of means to expand coverage and improve access to healthcare, the development of means of reducing healthcare disparities, and the development or improvement of methods of payment or coverage policies.
- Activities falling under paragraph (2) of the definition of "health care operations" under 45 CFR § 164.501: "Reviewing the competence or qualifications of health care professionals; evaluating practitioner and provider performance, and health plan performance; conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers; training of non-health care professionals; accreditation, certification, licensing, or credentialing activities."
- Activities that qualify as "treatment" under 45 CFR § 164.501.
- Activities that qualify as "fraud and abuse detection or compliance activities" under 45 CFR § 164.506(c)(4)(ii).

The authorized user is prohibited from using or disclosing the QE data or non-public analyses containing PHI for marketing purposes. The authorized user is also prohibited from redisclosing or making public any QE data or non-public analyses containing PHI.

[14] In cases where all the terms of the QE DUA at 42 CFR § 401.713(d) are contained in a contractually binding agreement between the qualified entity and the authorized user, the qualified entity is not required to re-paper that agreement as a QE DUA.

All other uses and disclosures of the QE data or non-public analyses containing PHI by authorized users are forbidden, with two exceptions. First, at the QE's discretion, the QE may permit an authorized user that is a provider or a supplier to redisclose QE data or non-public analyses in the same way that a HIPAA covered entity is permitted to disclose PHI under 45 CFR § 164.506(c)(4)(i), 45 CFR § 164.506(c)(2), or 45 CFR § 164.502(e)(1). Second, authorized users may be required to redisclose QE data or non-public analyses containing PHI as **required by law**, as defined at 45 CFR § 164.103.

Authorized users that receive beneficiary de-identified data (combined data or Medicare-only data) are prohibited from linking the beneficiary de-identified data to any other identifiable source of information and are prohibited from attempting any other means of re-identifying any individual whose data are included.

Privacy and Security Under the QE DUA

The QE DUA must contractually bind the authorized user to the following privacy and security protections for any data or analyses the authorized user receives under the QE DUA. The authorized user is required to ensure adequate privacy and security protection for the QE data and non-public analyses containing PHI. At a minimum, regardless of whether the authorized user is a HIPAA covered entity, such protections of beneficiary-identifiable data must be at least as protective as those required of covered entities and their business associates regarding PHI under the HIPAA Privacy and Security rules. In all cases, these requirements must be imposed for the life of such beneficiary-identifiable data or non-public analyses or any derivative data until all copies of such data or non-public analyses are returned or destroyed. These duties must be specified in such a manner as to survive termination of the QE DUA, whether for cause or not.

6.4.2 The Non-Public Analyses Agreement

A QE must enter into a contractually binding non-public analyses agreement with the authorized user (including any contractors or business associates described in the definition of authorized user) as a precondition of providing or selling de-identified non-public analyses. The non-public analyses agreement must contractually bind the authorized user (including any contractors or business associates described in the definition of authorized user) to the permissible uses of the analyses and the requirement to notify the QE of any violations of the non-public analyses agreement, and to cooperate in the QE's efforts to mitigate any harm that may result from such violations.

Permissible Uses Under the Non-Public Analyses Agreement

The non-public analyses agreement must prohibit the use of de-identified non-public analyses or derivative data for the following purposes:

- Marketing;
- Harming or seeking to harm patients or other individuals both within and outside the health care system regardless of whether their data are included in the analyses;
- Effectuating or seeking opportunities to effectuate fraud and/or abuse in the health care system;
- Publishing research reports.

If the authorized user is an employer, the authorized user may use the analyses or derivative data only for the purposes of providing health insurance to employees, retirees, or dependents of employees or retirees of that employer.

As part of the non-public analyses agreement, a QE may permit an authorized user that is a provider or a supplier to redisclose the de-identified analyses or derivative data, in the same way a covered entity is permitted to redisclose under 45 CFR § 164.506(c)(4)(i) or 45 CFR § 164.502(e)(1). If the authorized user

is not a provider or supplier, the authorized user may not redisclose or make public any non-public analyses or derivative data except as required by law.

The authorized user may not link the de-identified analyses to any other identifiable source of information and may not in any other way attempt to identify any individual whose de-identified data are included in the analyses.

6.5 QE Annual Reporting for Additional Uses of QE Medicare Data

QEs that choose to provide or sell QE data or non-public analyses must report additional information in their required QE annual report.

For non-public analyses provided or sold to authorized users, the QE annual report must include the following information:

- A summary of the analyses provided or sold, including:
  - The number of analyses;
  - The number of purchasers of such analyses;
  - The types of authorized users that purchased analyses;
  - The total amount of fees received for such analyses; and
  - Violations of the QE DUA or the non-public analyses agreement.
- A description of the topics and purposes of such analyses
- The number of analyses disclosed with unresolved requests for error correction.

For QE data provided or sold to authorized users, the QE annual report must include the following information:

- The entities that received QE data
- The basis on which each entity received such data
- The total amount of fees received for providing, selling, or sharing the data
- Violations of the QE DUA.

See Section 4.3 for additional information about the QE annual report requirements, including how to submit annual reports, and annual report due dates.

6.6 Violations of the CMS DUA or QE DUA

6.6.1 Assessments

In the case of a **violation** of the CMS DUA or the QE DUA, CMS may impose an assessment on the QE. CMS will calculate the amount of the assessment of up to $100 per Medicare Part A or B beneficiary whose data were implicated in the violation. For detailed information about the assessment amount and process, refer to 42 CFR § 401.719 (d)(5).

6.6.2 Termination of CMS DUA

CMS may terminate the QE's CMS DUA if the QE fails to ensure that authorized users comply with their QE DUAs or non-public analyses agreements.

Appendix A: Glossary

5% national sample files – The 5% random sample consists of Medicare beneficiaries who had a Medicare Health Insurance Claim (HIC) number equal to the Claim Account Number (CAN) plus the Beneficiary Identity Code (BIC) (HIC=CAN+BIC), where the last two digits of the CAN are in the set {05, 20, 45, 70, 95} at any time, beginning January 1, 1999. The HIC number is assigned by the Social Security Administration (SSA) when a person becomes eligible for benefits; however, the number may change over time if a person's reason for entitlement changes. The CAN number is the policy number of the wage earner who is eligible for benefits, which means that the CANs for spouses are joined. A marriage may cause a change in the HIC due to entitlement for benefits through the spouse. One variable is designed to make it easy to identify the random 5% sample for a particular year (the 5% flag—FIVEPCT); a second variable makes it possible to follow this sample longitudinally even when a HIC change causes the person to drop out of the 5% sample at a later point in time (the enhanced 5% flag—EFIVEPCT).

A

Acceptable Risk Safeguards (ARS) – The Centers for Medicare & Medicaid Services' (CMS) implementation for the selection and tailoring of the controls. The current version of the ARS is available in the CMS Information Security Library (http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html).

Additional Uses of QE Medicare Data – Expanded uses of QE Medicare Data under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The Rule, as required by MACRA, allows organizations approved as qualified entities to confidentially share or sell analyses of Medicare and private sector claims data to "authorized users:" providers, employers, and other groups that can use the data to support improved care. In addition, qualified entities may provide or sell claims data to providers and suppliers, such as doctors, nurses, and skilled nursing facilities among others. The Rule also includes strict privacy and security requirements for all entities receiving patient identifiable and beneficiary de-identified analyses or data, as well as expanded annual reporting requirements.[15]

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 data, 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.

Annual Report – An online module provided to QEs by the QECP team in order to collect the required annual reporting information.

Applicant – An entity who is in the process of submitting their Phase 1 application for QE certification, or has submitted their application and is awaiting a CMS certification decision.

Application – Comprised of all information submitted by entities during the application process, including general information, contact information, mailing address, self-assessments, text submitted in comment

[15] CMS Finalizes Rule Giving Providers and Employers Improved Access to Information for Better Patient Care. 07/01/2016. Available at: https://www.cms.gov/newsroom/press-releases/cms-finalizes-rule-giving-providers-and-employers-improved-access-information-better-patient-care

boxes, evidence/supporting documentation, data security plan of action and milestones (POAM) (if required), and signature.

Assessment – A statement describing the program requirement and performance expectations. The entity must demonstrate compliance with the assessment statement to meet the minimum requirements and receive approval for the element.

Attribution of Patient Services and Episodes – The application of specific rules to assign a particular patient's services or episodes to a specific provider.

Authorized User – A third party and its contractors (including, where applicable, business associates as that term is defined at 45 CFR §160.103) to which a qualified entity may provide or sell data or non-public analyses. Authorized users are limited to the following entities:

- A provider
- A supplier
- A medical society
- A hospital association
- An employer
- A health insurance issuer
- A health care provider and/or supplier association
- A state entity
- A federal agency

B

Beneficiary Identifiable – Any data or analyses that contain 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. *See also* **Patient Identifiable.**

C

Chronic Conditions 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 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 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 provider) claim type.

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

CMS Data Use Agreement (DUA) – A contractual agreement between 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.

Combined Data – At a minimum, a set of CMS claims data provided under the QE regulations (42 CFR § 401.701–401.722) combined with claims data, or a subset of claims data, from at least one of the other claims data sources described in 42 CFR § 401.707(d).

For the purposes of qualified clinical data registries acting as quasi qualified entities under the Qualified Entity Program requirements, combined data is defined as, at a minimum, a set of CMS claims data provided under 42 CFR Part 401, Subpart G, combined with clinical data or a subset of clinical data.

Composite Measure – A combination of two or more component measures, each of which individually reflects quality of care, into a single performance measure with a single score[16].

Control Family – Used in NIST Special Publication (SP) 800-53 and the CMS Acceptable Risk Standards (ARS) to organize and structure data security controls into logical families. Each family contains security controls related to the general security topic of that family. The QECP Phase 2 minimum requirements review is centered on these control families.

Corrective Action Plan (CAP) – Imposed as a result of the highest level of violation of QE program requirements. The CAP, provided by the QE, consists of both a remediation plan and evidence of remediation, which will be reviewed by relevant SMEs.

Corrective Action Plan (CAP) Request – A Corrective Action Plan (CAP) Request is issued by CMS to correct a compliance issue with a QE's performance under the QECP. A CAP Request describes the compliance issue, outlines the steps required to address the issue, sets a timeline by which the QE must address the issue, and specifies that QEs must track their progress toward CAP completion.

D

Data Breach – A data breach is a security incident in which sensitive, protected, or confidential data are copied, transmitted, viewed, stolen, or used by an unauthorized third party. A data breach may be intentional or unintentional.

Data Sources – The QE regulations (42 CFR § 401.703(h)) define claims data from other sources as "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." Qualified Clinical Data Registries (QCDRs) may use clinical data to meet the need for other data sources.

DUA Custodian(s)- Individuals who will have actual possession of the CMS data files, and who will be responsible for observance of all conditions of use, including the establishment and maintenance of security arrangements to prevent unauthorized use. This is a required role on the DUA and in rare instances may be the same individual as the Requester.

[16] Definition from NQF's Glossary of Terms:
https://www.qualityforum.org/Measuring_Performance/Submitting_Standards/NQF_Glossary.aspx

DUA Requestor- The person authorized to legally bind their organization to the terms specified in the DUA. This is a required role on the DUA.

E

Efficiency Measure – The cost of care associated with a specified level of health outcomes.[17]

Element – In order to determine an entity's compliance with the program requirements, the program requirements have been organized into a series of elements. Each element includes an assessment and evidence requirements.

Employer – Any person acting directly as an employer, or indirectly in the interest of an employer, in relation to an employee benefit plan; includes a group or association of employers acting for an employer in such capacity, as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974.

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 and allows reviewers to evaluate whether the entity meets the requirement.

F

Full Data Usage Rights – Sufficient usage rights, due to the qualified entity's own operations or disclosures from providers, suppliers, private payers, multi-payer databases, or other sources, to the other sources of claims data to allow the qualified entity to use that data for the purposes required and permitted under the QE program (including, but not limited to public reporting and calculating provider performance measures and combining other-payer data with Medicare FFS data).

G

H

Health Care Provider and/or Supplier Association – A nonprofit organization or association that provides unified representation and advocacy for providers and suppliers at the national or state level and whose membership is comprised of a majority of suppliers or providers.

Health Insurance Issuer – An insurance company, insurance service, or insurance organization (including a health maintenance organization) which is licensed to engage in the business of insurance in a State and which is subject to State law that regulates insurance, as defined in section 2791 of the Public Health Service Act.

Health Plan – An organization that acts as an insurer for an enrolled population.[18]

Health Insurance Portability and Accountability Act of 1996 (HIPAA) – The HIPAA Privacy Rule establishes

[17]Definition from NQF's Glossary of Terms:
https://www.qualityforum.org/Measuring_Performance/Submitting_Standards/NQF_Glossary.aspx
[18]Definition from NQF's Glossary of Terms:
https://www.qualityforum.org/Measuring_Performance/Submitting_Standards/NQF_Glossary.aspx

national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients' rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.
For more information, visithttps://www.hhs.gov/hipaa/for-professionals/privacy/index.html.

Hospital Association – A nonprofit organization or association that provides unified representation and advocacy for hospitals or health systems at a national, state, or local level and whose membership is comprised of a majority of hospitals and health systems.

I

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 CMS Data Use Agreement (DUA), minimum requirements, monitoring, and ongoing program administration.

M
Marketing – A communication about a product or service that encourages recipients of the communication to purchase or use the product or service, as defined by 45 CFR § 164.501. Marketing is also defined as an arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Measure (***see*** **Alternative Measure**, **Composite Measure**, **Efficiency Measure, Quality Measure, Resource Use Measure, Standard Measure**)

Medical Society – A nonprofit organization or association that provides unified representation and advocacy for physicians at the national or state level and whose membership is comprised of a majority of physicians.

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 groups (DRG), 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 variables such as level of hospice care received [e.g., routine home care, inpatient respite care], terminal diagnosis code, dates of service, reimbursement amount, and provider number)
- *Home Health* – From home health care providers (includes variables such as number of visits, types of visit, diagnosis codes, 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)
- *Durable Medical Equipment Regional Carrier* – From durable medical equipment suppliers (includes variables such as 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 elements that an entity must meet to become certified as a qualified entity. These requirements are derived directly from the QE regulations (42 CFR § 401.705–401.717).

Monitoring Review – A review that may occur at any time after a QE has obtained QE Medicare data. The purpose of this review is to ensure QE compliance with selected elements related to data security, measurement, reporting, and the corrections and appeals process as described and approved in the QECP application. As referenced in the QE regulations (42 CFR § 401.719), monitoring may include an onsite visit to review the documented and physical evidence submitted for the selected standards.

N

O

Ongoing Program Administration (OPA) – A mechanism by which the QECP team observes QEs' compliance with all QECP elements throughout their 3-year QE certification period. During OPA, the QECP team will interact with all certified QEs to provide ongoing program support; communicate with QEs about any deficiencies that were identified and resolved during the minimum requirements review, any monitoring reviews, and any CAPs that were required; and interact with QEs that report changes in key aspects of their program, such as adding measures. As part of OPA, the QECP team also will review QEs' annual reports.

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

P

Patient-Identifiable - Any data or analyses that contain the patient's name, Medicare Health Insurance Claim Number (HICN), or any other direct identifying factors including, but not limited to, postal address or telephone number. *See also* **Beneficiary Identifiable**.

Personally Identifiable Information (PII) – Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.

Program Guide – A comprehensive document that describes QECP operations and policies, including all CMS requirements that entities and certified QEs must meet, as well as an overview of the application process. The Program Guide is revised and released annually in its entirety.

Program Manager (PM) – The QECP staff member who is the entity's primary point of contact throughout the QECP process and who is responsible for validating the completeness of all materials submitted for QECP review, assigning the entity to a review team, assisting the entity throughout its QECP participation, and facilitating contact between the entity and the QECP team.

Protected Health Information (PHI) - Individually identifiable health information. For more information see HIPAA regulations at 45 CFR 160.103.

Providers – The term used to collectively refer to providers of services and suppliers. Providers' performance will be calculated and publicly reported by QEs.

Providers of Services – A provider is defined in 42 CFR § 400.202 as "a hospital, a CAH [critical area hospital], a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services."

Public Reporting – Primary purpose of the QE program, wherein QEs must release public provider performance analyses annually based on combined other-payer and QE Medicare data, using standard or approved alternative measures. The reports must include a description of the measures used that can be

easily understood by consumers.

Q

Qualified Clinical Data Registry (QCDR) – An entity meeting the requirements promulgated under the Social Security Act §1848 (m)(3)(E). A Centers for Medicare & Medicaid Services (CMS)-approved QCDR is an entity that collects clinical data from MIPS clinicians (both individual and groups) and submits it to CMS on their behalf for purposes of MIPS. The QCDR reporting option is different from a qualified registry because it is not limited to measures within the Quality Payment Program. The QCDR can develop and submit for CMS approval, QCDR measures (formally referred to as non-MIPS measures within the CY 2017 Quality Payment Program final rule).

Qualified Entity (QE) – A single public or private entity, or a lead entity and its contractors, or, if the entity 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 on measures of quality, efficiency, effectiveness, and resource use, and (2) agrees to meet the regulatory requirements in 42 CFR § 401.701–401.722.

Qualified Entity Certification Program (QECP) – The product of the QE regulations (42 CFR § 401.701–401.722), which was developed so that interested entities that successfully meet the criteria outlined in the QE regulations may become certified as qualified entities and maintain their QE status.

Qualified Entity Data Use Agreement (QE DUA) – A data use agreement between a QE and an authorized user that contains specific provisions as required in the QE regulations (42 CFR § 401.713(d)) and is required as a precondition of a QE providing or selling combined data or non-public analyses, or providing Medicare data at no cost, to an authorized user.

Quality Measure – Numeric quantification of health care quality for a designated health care provider, such as a hospital, health plan, nursing home, clinician, etc.[19]

Quasi QE – A qualified clinical data registry that agrees to meet all the requirements in 42 CFR Part 401, Subpart G, with the exception of § 401.707(d), may request access to Medicare data as a quasi qualified entity in accordance with such qualified entity program requirements.

QE Medicare Data – The standardized extracts of Medicare Parts A and B claims data and Part D prescription drug event (PDE) data that a QE is eligible to receive under the CMS DUA.

QE Regulations – 42 CFR Part 401, Subpart G, § 401.701–401.722, Availability of Medicare Data for Performance Measurement, implements Section 10332 of the Affordable Care Act regarding the release and use of standardized extracts of Medicare claims data for qualified entities to measure the performance of providers of services (referred to as providers) and suppliers. The regulation explains how entities can become qualified by CMS to receive standardized extracts of claims data under Medicare Parts A, B, and D for the purpose of evaluating the performance of providers and suppliers. This rule also lays out the criteria qualified entities must follow to protect the privacy of Medicare beneficiaries.

[19] Definition from NQF's Glossary of Terms:
https://www.qualityforum.org/Measuring_Performance/Submitting_Standards/NQF_Glossary.aspx

For more information visit http://www.gpo.gov/fdsys/pkg/FR-2011-12-07/pdf/2011-31232.pdf; amends made July 1, 2016, are available at http://federalregister.gov/a/2016-15708.

QECP Data Security Workbook – A Microsoft Excel workbook that must be submitted by QEs in order to pass Phase 2 of the QECP minimum requirements review.

QECP Online Application – 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

Reapplication – Process undergone by a QE in good standing 6 months before the end of its 3-year certification approval period in order to continue receiving QE Medicare data. As part of reapplication, QEs must submit documentation of any changes to their previously approved application.

Reliability – The repeatability or precision of measurement. Reliability of data elements refers to repeatability and reproducibility of the data elements for the same population in the same time period. Reliability of the measure score refers to the proportion of variation in the performance scores due to systematic differences across the measured entities (signal) in relation to random variation or noise.[20]

Required by Law – A mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law, as defined by 45 CFR 164.103. Required by law includes, but is not limited to:

- Court orders and court-ordered warrants
- Subpoenas or summons issued by a court
- Grand jury
- Governmental or tribal inspector general
- Administrative body authorized to require the production of information
- Civil or authorized investigative demand
- Medicare conditions of participation with respect to health care providers participating in the program.
- Statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

Resource Use Measure – Comparable measures of actual dollars or standardized units of resources applied to the care given to a specific population or event—such as a specific diagnosis, procedure, or type of medical encounter.[21]

Review – Activity performed by the QECP team to evaluate whether an entity meets the program requirements, either for the initial application for certification, monitoring after certification, or reapplication for recertification.

[20] Definition from NQF's Glossary of Terms: https://www.qualityforum.org/Measuring_Performance/Submitting_Standards/NQF_Glossary.aspx

[21] Definition from NQF's Glossary of Terms: https://www.qualityforum.org/Measuring_Performance/Submitting_Standards/NQF_Glossary.aspx

Review Team – Inclusive of the QECP Program Manager, administrative reviewer, and executive reviewer. All members of the review team must have specific educational and experience qualifications.

S

Self-assessment – The independent decision of entities regarding whether or not they meet the requirements described in the QE application. While submitting supporting documentation for each element during the application process, entities must answer "yes," "no," or "not applicable" in the self-assessment field to indicate whether they meet the requirements for the element and must provide an explanation in the comment box.

Standard Measure – A measure that is calculated in full or in part from claims data from other sources and the standardized extracts of Medicare Parts A and B claims data and Part D prescription drug event (PDE) data. The measure must fall into one of the following categories: the 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 [NQF]); the measure is currently being used in a CMS program that includes quality measurement; or the measure is endorsed by a CMS QE Consensus Based Entity (CBE).

Standardized Extracts – Medicare Parts A and B claims data and Part D prescription drug event (PDE) data representing 100 percent of the claims in the Chronic Conditions Data 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 CMS DUA and receipt of payment for fees.

State Entity - Any office, department, division, bureau, board, commission, agency, institution, or committee within the executive branch of a state government.

Suppliers – 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 and whose performance will be calculated and publicly reported by QEs.

T

Technical Correction - A Technical Correction request is issued by CMS to correct a compliance issue with a QE's performance under the QECP. A Technical Correction describes the compliance issue, outlines the steps the QE needs to take to come back into compliance, and sets a timeline by which the QE must address the issue.

U

V

Validation – The first step taken by the QECP team in reviewing an application for QE certification, which ensures that all self-assessments are complete, evidence has been provided for all applicable elements, and contact information is complete as submitted. If the application is "valid" and therefore deemed to be complete, the administrative and executive reviews commence. If an application does not pass validation, the entity's Program Manager will contact the entity for additional information or evidence.

Validity – Refers to the correctness of measurement. Validity of data elements refers to the correctness of the data elements as compared to an authoritative source. Validity of the measure score refers to the correctness of conclusions about quality that can be made based on the measure scores (i.e., a higher

score on a quality measure reflects higher quality).[22]

Violation – A failure to comply with a requirement of a DUA. A QE may not, under any circumstances, use a measure, create a report, or issue a report after a violation of the DUA until the QECP team receives and reviews the notification of the violation and informs the QE of any changes to its relationship with CMS, including whether the QE's DUA has been terminated.

W

X

Y

Z

[22] Definition from NQF's Glossary of Terms: https://www.qualityforum.org/Measuring_Performance/Submitting_Standards/NQF_Glossary.aspx

Appendix B : QECP Resources

Resource	Description and Purpose	Location
QECP Helpdesk email	Contact a Program Manager	support@QEMedicareData.org
QECP Webpage	Provides general information about the Medicare Data Sharing Program, the QE application, frequently asked questions (FAQs), and educational QECP webinar recordings	http://www.QEMedicareData.org
QECP Password Resets and Changing User Access to the Online Portal	To grant or change your organization`s user access to the QECP online portal or to reset your password; please contact your program manager	support@qemedicaredata.org
QECP Portal Users Guide	A guide to the QECP Application	https://www.qemedicaredata.org/resource/1570803370000/QECPPortalUserGuide
Patient Protection and Affordable Care Act (see Section 10332)	The Affordable Care Act of 2010 includes a provision for the Secretary to make available to qualified entities standardized extracts of Medicare claims data under Parts A, B, and D for the purpose of measuring health care provider and supplier performance.	http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590pp/html/BILLS-111hr3590pp.htm
QE regulations (42 CFR §401.701-401.722)	The QE regulations establish the requirements of the QECP and the QE CBEC Program.	https://www.gpo.gov/fdsys/pkg/FR-2011-12-07/pdf/2011-31232.pdf
Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (see Section 105)	The final rule expands how QEs may use and disclose data under the program. This rule explains how QEs may create non-public analyses and provide or sell such analyses to authorized users, as well as how qualified entities may provide or sell combined data, or provide Medicare claims data alone at no cost, to certain authorized users.	https://www.federalregister.gov/documents/2016/07/07/2016-15708/medicare-program-expanding-uses-of-medicare-data-by-qualified-entities
ResDAC webpage on the Qualified Entity Program	General information about the Medicare Data Sharing Program, CMS Data Use Agreement instructions, payment processing, Medicare data training opportunities, and data corrections procedures	https://www.resdac.org/requester/qualified-entity

CMS webpage on the Qualified Entity Program	CMS general information page for the Medicare Data Sharing Program, which also directs individuals to the appropriate resources for applying to become a QE and requesting QE Medicare data	http://www.cms.gov/QEMedicareData

QECP Webinars

Webinar	Description and Purpose	Location
QE 101	Provides an overview of the QECP	QE 101 Webinar (QECP website → Application tab → Webinars → QE 101 Webinar)
Salesforce Webinar	Provides an overview of the QECP Salesforce application	Salesforce Webinar (QECP website → Application tab → Webinars → QECP Salesforce Webinar)
Phase 1	Provides an overview of Phase 1 of the QECP application	Phase 1 Webinar (QECP website → Application tab → Phase 1 Header →Webinars →Phase 1 Webinar)
Phase 2	Provides an overview of Phase 2 of the QECP application	Phase 2 Webinar (QECP website → Application tab → Phase 2 Header →Webinars →Phase 2 Webinar)
	Provides an overview of the new ARS 3.1 data Security requirements	Phase 2 Webinar (QECP website → Application tab → Phase 2 Header →Webinars →ARS 3.1 Webinar)
Phase 3	Provides an overview of Phase 3 of the QECP application	Phase 3 Webinar (QECP website → Application tab → Phase 3 Header →Webinars →Phase 3 Webinar)
Annual Report	Provides a guide to the Annual Report instructions	Annual Report Webinar (QECP website → QE Program Information tab → Ongoing Program Administration Header →Webinars → QE Annual Report Webinar)
Permissible Uses of Data	Provides an overview of Section 105 of MACRA and its implications for QEs, including permissible uses of QE Medicare data	Permissible Uses of Data Webinar (QECP website → QE Program Information tab → Uses of Medicare Data Header →Webinars →Permissible Uses of Data Under the QE Program Webinar)
Data Dissemination	Provides an understanding about the QE data dissemination process and additional information on	Data Dissemination Webinar (QECP website → QE Program Information tab → Data Availability and Cost Header →Webinars →Data Dissemination and Integration)

	processing Medicare claims and prescription drug event data sets	
DUA	Provides an overview of the CMS data use agreement specific to the QECP	DUA Webinar (QECP website → Application tab → Phase 2 Header →Webinars →DUA Webinar)

QECP Tip Sheets

Tip Sheet	Description and Purpose	Location
Uses of Medicare Data	Provides information on data use, applicable users, and required contractual agreements for use of the QE Medicare data as part of the QECP	Uses of QE Medicare Data Tip Sheet Permissible Uses of Data Webinar (QECP website → QE Program Information tab → Uses of Medicare Data Header →Toolkits →Uses of QE Medicare Data Tip sheet)
QE Public Reporting	Provides information on ensuring QE program compliance when producing and publishing public reports	QE Public Reporting Tip Sheet (QECP website → Application tab → Phase 3 Header →Toolkits →QE Public Reporting Tip Sheet)