QECP FREQUENTLY ASKED QUESTIONS (FAQS)

Application

How can I obtain information about other Medicare data sharing programs, such as the state agency research program?

For information on all CMS data release programs, visit the Research Data Assistance Center's (ResDAC's) "CMS Data" page: http://www.resdac.org/cms-data. You can also contact ResDAC directly at 1-888-9RESDAC, or resdac@umn.edu.

Is there a deadline for submitting an application?

There is no deadline for submitting applications for Phase 1 and Phase 2 certification; applications are accepted by CMS on a rolling basis. However, CMS requires that QEs obtain Phase 3 certification and release their first public performance report within one year of receiving the QE Medicare data.

More information is available at:

http://www.cms.gov/QEMedicareData

https://www.resdac.org/requester/qualified-entity

http://www.qemedicaredata.org

Are there limits to the types of organizations that can apply to become QEs?

No, any entity that satisfactorily meets the eligibility requirements defined in 42 CFR 401.703(a) (either itself or through contracts with other entities) can participate in the QE program. CMS has not limited the types of organizations that may serve as qualified entities. All organizations that meet the application requirements will be considered without regard to organization type.

Can multiple entities from the same region apply to become QEs?

Yes, multiple entities from the same region can apply to become a QE. If there are multiple organizations in an area that could serve as individual QEs, these organizations could decide to form contractual arrangements with each other and apply for the program under a lead applicant.

What is a quasi Qualified Entity (quasi QE) and how is the quasi QE certification process different from the regular QE certification process?

A quasi QE is a Qualified Clinical Data Registry (QCDR) that meets all of the QECP program requirements, with some exceptions. Quasi QEs are exempt from meeting the requirements for Element 1.3 (Experience), parts of Element 1.4 (Claims Data) and, in certain cases, all requirements associated with Phase 3.

To become a quasi QE and receive QE Medicare data, QCDRs will need to follow the same phased minimum requirements review process as other organizations seeking QE certification, with the requirement exceptions noted above. Additionally, for QCDRs acting as quasi QEs, combined data refers to CMS claims data provided through the QE Program, combined with clinical data or a subset of clinical data.

QCDRs that apply for and meet the set of minimum requirements, obtain and execute a CMS Data Use Agreement (DUA), pay the associated fee for data extraction and delivery, and comply with the annual public reporting and ongoing program administration activities are deemed quasi QEs and are certified for 3 years.

To apply to become a quasi QE, QCDRs should register on the QECP public website, www.qemedicaredata.org and complete a registration form. For more information on QCDRs, see the QCDR User Guide.

Data Availability and Cost

For which states and territories are QEs eligible to receive data under the QECP?

Depending on QEs other sources of claims data and reporting regions, QEs are eligible to receive regional, state, and national (all 50 states and the District of Columbia) data files.

For the purposes of calculating covered lives, can Managed Medicaid subscribers, Tricare plan subscribers, or Medicare Supplemental Insurance subscribers be excluded from the numerator and denominator?

Tricare plan subscribers and/or Managed Medicaid subscribers cannot be excluded from covered lives calculations. Because Medicare Supplemental Insurance is used in combination with Medicare and the Medicare Supplemental Insurance subscribers are Medicare beneficiaries, only these covered lives may be excluded from the covered lives calculation.

Which data sets can QEs request under the QE program, and where can I find additional information for the available data sets, such as the data dictionary?

Certified QEs may request data for one or more of the following data sets for the previous 3 years if the QE has other payer data for the geographic area:

- Inpatient Claims
- Outpatient Claims
- SNF Claims
- Hospice Claims
- Home Health Claims
- Carrier Claims
- DMERC Claims
- Part D Events
- Plan Characteristics (included with Part D Event)
- Pharmacy Characteristics (included with Part D Event)
- Prescriber Characteristics (included with Part D Event)
- Beneficiary Summary File (Medicare beneficiary demographics and enrollment data)

In order to estimate benchmarks, certified QEs may also, upon approval, obtain a 5% national sample of any of the above claims files.

Data dictionaries for these CCW data sets may be found as embedded hyperlinks in the QE Medicare Data Specifications Worksheet: http://www.resdac.org/cms-data/request/materials/qe-specifications-worksheet.

Are substance use disorder [Substance Abuse and Mental Health Services Administration (SAMHSA)] claims included in the Medicare data provided to QEs?

Yes, beginning in June 2017, QEs receive SAMHSA claims in their QE data sets. However, QEs must redact all SAMHSA claims from beneficiary-identifiable data or beneficiary-identifiable non-public analyses prior to sending to an authorized user. It is the responsibility of the QE to redact SAMHSA claims when necessary. QEs will receive a crosswalk file that identifies SAMHSA claims to assist with redaction.

QEs that previously received redacted CMS claims files will be able to purchase the missing SAMHSA claims and crosswalk file, in the form of "gap" files. If your organization is interested in requesting "gap" files, please contact ResDAC directly at 1-888-9RESDAC, or resdac@umn.edu.

How are QEs permitted to use and disclose substance use disorder [Substance Abuse and Mental Health Services Administration (SAMHSA)] claims?

QEs are permitted to use SAMHSA claims when:

- Publishing public reports on the performance of providers and suppliers;
- Providing or selling beneficiary de-identified non-public analyses to authorized users; and
- Providing or selling beneficiary de-identified combined data or providing beneficiary de-identified Medicare data at no cost to authorized users.

However, QEs must redact all SAMHSA claims from beneficiary-identifiable data or beneficiary-identifiable non-public analyses prior to sending to an authorized user.

Please contact your PM at support@qemedicaredata.org with any questions about permissible uses and disclosures of SAMHSA claims.

Do QEs receive a standard set of PDE variables, or can they choose the PDE variables that best suit their needs?

Beginning in June 2017, QEs can select the PDE variables that best suits their needs or continue to receive the standard set of PDE variables that were included in previous data requests. QEs must complete the PDE variable justification tab of the QE Specifications Worksheet in order to select the PDE variables, even if they wish to receive the same set of variables.

QEs can contact ResDAC directly at 1-888-9RESDAC, or resdac@umn.edu with questions about PDE variables or to obtain a list of the variables the QE has received in the past.

What fiscal data are included in the Medicare Part D claims?

The contents of the Part D file can be found here: https://www.ccwdata.org/web/guest/data-dictionaries

Are denied claims included in QE Medicare data? If so, is there a field that identifies claims as denied and how should we exclude them from the QE Medicare data?

Yes, the QE Medicare data files contain denied claims. Within the Carrier and Durable Medical Equipment (DME) files, QEs can identify denied claims by looking at the "Carrier Claim Payment Denial Code" (PMTDNLCD) variable, equal to zero ("0") Denied or "D" Denied due to demonstration involvement.

To exclude denied line items in the Carrier and DME files, include only those line items with "Line Processing Indicator Code" (PRCNGIND) equal to "A" Allowed, or "R" Reprocessed, or "S" Secondary payer and the "Line Allowed Charge Amount" (LALOWCHG) greater than $0.

To identify a fully denied institutional claim, use the variable "Claim Medicare Non-Payment Reason Code" (NOPAY_CD) equal to anything other than "blank." The NOPAY_CD variable identifies only a small fraction of denied services. For another strategy, look at claims with zero payment amounts and then check the revenue center information. To identify the denied revenue center lines, use the "Revenue Center Non-Covered Charge Amount" (REV_NCVR) variable equal to "Revenue Center Total Charge Amount" (REV_CHRG). Revenue center payment or line item payments equal to $0.00 could indicate a non-covered service, a covered service in which Medicare's responsibility is $0.00 due to deductibles or another primary payer, or it could

indicate a code required on the claim that has no payment attached to it (e.g., location of care Healthcare Common Procedure Coding System (HCPCS) codes for hospice claims).

Finally, the following scenarios can also indicate that a claim was not covered or denied:

- Condition code of 20 or 21
- Non-covered charges > $0.00
- HCPCS modifiers GA, GX, GY, and GZ PLUS a $0.00 line item or revenue center payment"

Do the CMS data include Medicare as both the primary payer and the secondary payer?

Yes, the claims data will include Medicare as both the primary payer and the secondary payer. If a Medicare beneficiary has another primary payer, such as an employer-sponsored health plan, the claims will include variables to show both the amount paid by the primary payer and the Medicare payment amount.

In the case of a dual eligible beneficiary, the claims will primarily be found in the Medicare files, except for those services that are not covered under the Medicare program, for example, nursing home coverage. In that case, the claims for nursing home coverage would appear in the Medicaid claims.

How will QEs link beneficiary information from their commercial claims dataset with the QE Medicare dataset?

In addition to the information in the Master Beneficiary Summary File for Parts A/B/C/D, QEs can request the following crosswalks to link the QE Medicare data to other data sources:

- BENE ID to HIC
- BENE ID to MBI
- BENE ID to SSN
- BENE ID to Name

Passing the Phase 2 data security requirements of the QECP program and completing a CMS DUA enable QEs to receive and incorporate QE Medicare data at the beneficiary level. For more information about crosswalks and linking the QE Medicare data, please contact ResDAC directly at 1-888-9RESDAC, or resdac@umn.edu.

Can my organization obtain a current cost estimate for the Medicare data available under this program? When will the payment be due?

Yes. Cost information on the Medicare data files available under the QE program can be found here. QEs will receive a final cost estimate after they receive their Phase 2 (Data Security) certification and DUA approval.

Payment is due within 5 business days of receiving the final Medicare data cost invoice. Data will be prepared and released to QEs only after payment has been successfully processed.

Where can I find more information about the QE data request process?

Specific information about initiating the QE data request process may be found at https://www.resdac.org/requester/qualified-entity. ResDAC will assist certified QEs with the data request process. In addition, ResDAC can provide technical assistance to:

- Determine which CMS data files are appropriate for the requestor's needs
- Clearly define the data request
- Provide general information about services available at ResDAC regarding the use of CMS data
- Assist with technical questions related to use of the QE data sets.

What size are the state- and regional-level data files?

The size of the state-level data files varies from approximately 7GB to 500GB. The size of the regional-level data file varies depending on the county cohorts.

What is the file format of the Standard Extract?

RIF data files will be delivered in a fixed-column format with SAS programs (for SAS users) and FTS files (for non-SAS users). More information on the record layouts and codebooks for data files can be found here: https://www.ccwdata.org/web/guest/data-dictionaries.

Is it possible to obtain a data sample from CMS that is structured exactly like the deliverable (same number of files, file structure, compressed format)?

No, sample files are not available for the QE program. Record layouts and data dictionaries for the files can be found here: https://www.ccwdata.org/web/guest/data-dictionaries

However, an organization interested in becoming a QE may find it beneficial to review the CMS Medicare FFS/Part D Public Use Files (http://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SynPUFs/index.html).

The intent of the Data Entrepreneurs' Synthetic Public Use Files (De-Syn PUFs) is to give users a sense of the way in which certain variables behave; however, they represent a very small subset of the files. ResDAC and the QECP team do not recommend use of the De-Syn PUFs to develop code to import the full files. The De-Syn PUFs should be used only to simulate what the user is likely to find in the full files.

For a comparison of the different types of data files (RIF, LDS, and PUF), please refer to this ResDAC knowledgebase article: https://www.resdac.org/articles/differences-between-rif-lds-and-puf-data-files

What are the data delivery options for national QE Medicare data?

National QE Medicare data files (Parts A, B, and D) will be 4–5.5 TB in size per year and may be transmitted by external hard drive or SFTS. Quarterly national data files will be approximately 1 TB in size, and may also be transmitted via external hard drive or SFTS. SFTS performance will depend on the size of the files and the organization's bandwidth connections. The minimum SFTS operating requirements are:

1. Supported browsers: Current version and two previous versions of Microsoft Internet Explorer (e.g., 11.x, 10.x), Mozilla Firefox, or Google Chrome
2. Broadband Internet connection

How long will it take to receive a year's worth of national data?

Due to the large file size and complex file structure, the estimated timeframe for extracting and shipping each year of national QE Medicare data (excluding Part D data) will be 30 days. The estimated timeframe for extracting and shipping each year of national QE Medicare data that includes Part D will be 8 weeks.

Can we break up the national QE Medicare data delivery into 1-year segments?

Yes, the national QE Medicare data can be extracted and shipped in 1-year segments.

Will we receive a single hard drive or multiple hard drives?

It depends on how the QE chooses to receive the data. If the QE wishes to receive the data in 1-year segments, it will receive multiple hard drives (one every 30 days if the extract excludes Part D data or, one every 8 weeks if the extract includes Part D data), each containing one year of national data. If the QE chooses to receive several years of data at once, it will receive a single hard drive containing multiple years of national data. The QE will receive this single data delivery within a period of either 30 days (for extracts excluding Part D data) times the number of years requested or, 8 weeks (for extracts including Part D data) times the number of years requested.

Are the source data compressed, and what is the compression ratio?

Yes, the data are compressed, and the compression ratio is approximately 80-90%.

The QE regulations state that information on individual providers can only be publically released in aggregate form. What exactly does this mean? Can you provide an example?

This excerpt of the QE regulations means that all results calculated for providers and suppliers must be aggregated and reported at a level higher than the patient level. Information on individual beneficiaries may NOT be disclosed. No individual patient should ever be placed at risk for identification based on results presented in a public report.

Example: When a provider's influenza immunization rate for CY 2010 is reported to the public, the result should be expressed following the specifications of the standard measure (which includes a minimum sample size). For example, 80 percent of Dr. Smith's patients received an influenza immunization during CY 2010. Releasing a list of patients (for example, those patients with or without an influenza immunization) in a public report, or in any form in which someone could identify a patient, is strictly prohibited.

Ongoing Program Administration (OPA)

After an organization becomes a Certified QE, is it required to report changes to information submitted as part of its application? Is there an established process that the QE should follow if it needs to report a change?

Yes, after an organization is certified as a Qualified Entity, it may wish to modify its program operations that were approved based on its application. Because changes to the QE's processes or systems may impact the QE's ability to meet the minimum requirements established in the QECP, all such changes must be reported to the QECP team.

All changes that must be reported to the QECP team are detailed in Section 2. QECP Program Guide, including QECP reporting changes requirements, the timeframe in which each change must be reported, and supporting documentation that QEs may be required to submit to support the reported change.

What is considered a significant change in a data security program under the QECP?

A significant change is defined in NIST Special Publication (SP) 800-37 as a change that is likely to affect the security state of an information system or its environment of operation. The examples listed below are significant only when they meet the threshold established in the NIST definition above.

Significant changes to an information system include:

- Installation of a new or upgraded operating system, middleware component, or application;
- Modifications to system ports, protocols, or services;
- Installation of a new or upgraded hardware platform;
- Modifications to cryptographic modules or services; or
- Modifications to security controls.

Examples of significant changes to the environment of operation may include, but are not limited to:

- Moving to a new facility;
- Change in vendors, business partners, or service providers;
- Changes in data hosting providers;
- Changes in internet service providers used to transmit QE Medicare data;
- Changes in staff with primary responsibility for data security;
- Adding new core missions or business functions;
- Data breaches and other violations of the CMS DUA;
- Adding or removing individuals from 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.

What are examples of documentation that a QE would be required to submit in the event of a significant change in their data security program?

In the event of a significant change in the QE's data security program, examples of documentation that a QE may be required to submit to the QECP team include:

- Risk assessments
- Security impact assessments
- Pre/post production system functionality testing/data validation
- Information system design documentation
- Configuration management records
- Change request form(s)
- Attestation/confirmation that QE Medicare data backups are available if data reset is required when reverting a system to a previous version as a result of a failed upgrade or data transfer
- Updated QECP Data Security workbook with revised supporting evidence
- Updated data flow and/or physical network diagram.
- Business Associate Agreement (BAA) with new hosting provider or Cloud Service Provider (CSP)
- Evidence delineating the responsibilities of the QE versus the responsibilities of the CSP
- Other service agreement(s)
- Certificate of Disposition (COD)

When is a change in vendor, business partner, or service provider considered a significant Data Security (Phase 2) reported change versus an Entity (Element 1.1: Change in Contractual Relationships) reported change?

A change in vendor, business partner, or service provider is considered a significant data security change (i.e., QECP Phase 2 reported change) if the change is experienced by a lead QE or QE

contractor that has access to the identifiable QE Medicare claims data, has submitted a QECP Phase 2 Data Security Workbook, and was deemed Phase 2 compliant by CMS.

Changes to a lead QE's contractors must be reported to the QECP team as an Entity (Element 1.1) reported change. If a QE's Entity (Element 1.1) contractor change involves organizations with access to identifiable QE Medicare claims data, the lead QE's Phase 2 certification status will be revoked (if previously achieved) and the new contractor will be required to submit a QECP Data Security Workbook and related Data Security (Phase 2) supporting documentation

When must QEs release their first QE public performance report?

QEs are expected to release their first QE public performance report within one year of receiving QE Medicare data. QEs are expected to release public performance reports annually thereafter.

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.

In order to request a public reporting extension, QEs must submit a formal letter to CMS. The extension request letter must include:

- the QE's original timeline,
- the new estimated target date for the release of the QE's first QE public performance report,
- a rationale for why an extension request letter is needed, and
- an explanation of how the QE Medicare data have been used by the QE and its contractor (if applicable) since that data were received.

QEs required to submit a formal extension request letter should use the Contact Form to request a letter template from the QECP team.

Are there additional approaches to public reporting that comply with QECP requirements?

Yes. Described below are some additional approaches to public reporting that comply with QECP requirements. As a reminder, CMS has not (and does not plan to) prescribe a uniform QECP corrections and appeals model that all QEs must implement. As part of Element 2.3, QEs must explain the corrections and appeals process that will work best for their community/geographic reporting area while still adhering to QECP requirements.

Example 1 (Longer than 60-day C&A Period):

While the Final Rule requires at least 60 calendar days for provider corrections and appeals prior to publicly reporting measure results, a QE can designate a period longer than 60 calendar days for the provider corrections and appeals process. QEs may choose this approach to allow additional time for providers to request corrections for inclusion in the QE's public report.

Example 2 (More than one C&A Period):

A QE may conduct more than one 60-day provider corrections and appeals period prior to public reporting as long as:

1. The measures calculated with QE Medicare data are included in all corrections and appeals periods, and these measures are ultimately publicly reported;
2. The QE Medicare data used to calculate measures included in the first round of reports distributed to providers are also used to calculate measures in the next report distributed to providers, which is subsequently publicly reported; and
3. The QE is compliant with the Final Rule, which requires QEs to release public reports at least annually.

QE may release a report to providers that uses claims data service dates of January–June 2014, followed by a subsequent report to providers that uses service dates of January–December 2014. After both rounds of confidential provider corrections and appeals, the QE must publicly report the January–December 2014 measure results.

Please note that if a QE chooses to pursue this option, it is the QE's responsibility to ensure that measure specifications are followed appropriately. If this approach changes the definition of a measure from standard to alternative, the QE must submit documentation to the QECP team that demonstrates the stakeholder consultation approval process has been conducted and that justifies the use of the alternative measure.

Example 3 (Simultaneous Public Release of Two Cycles of Results):

A QE may choose to delay publication of a cycle of provider performance results and publish two cycles of results simultaneously. While results from both cycles must ultimately be released publicly, a QE may choose to display the results of a particular cycle more prominently. For example, on the same day, Cycle 2 results (using 2014 claims data service dates) might be published prominently on the QE's web page, while Cycle 1 results (using 2013 claims data service dates) might be published on a "historical performance information" web page. Since QEs are expected to release their first QE public performance report within one year of receiving QE Medicare data, this approach may require that the QE submit a letter to the QECP team requesting an extension of the public reporting requirement.

Phase 1

What are the expectations and requirements for demonstrating at least 3 years of experience (Element 1.3)?

An entity applying to be a QE must demonstrate 3 or more years of experience combining claims data, accurately calculating measures, verifying data, using a corrections process, and public reporting. QEs may choose to partner with other organizations or contractors to comply with this requirement. 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.

Can Quality Improvement Organizations (QIOs) operate both as a QE and as a QIO?

Yes, CMS has determined that an organization that has a QIO contract may also become a QE. However, the entity may not perform any QE-related work under the QIO contract or use QIO-allocated resources. Therefore, QIOs may not use their existing Standard Data Processing System (SDPS) to house QE data. In addition, QIOs must pay particular attention to the confidentiality and conflict of interest clauses in their QIO contract to ensure that their work as a QE will not conflict with their work as a QIO.

Can QIOs re-use the data they receive under their QIO contract to conduct QE-related work?

Yes, QIOs are permitted to re-use Medicare FFS claims data for the QE program; however, not all of the file types that are part of the QE data sets are provided to QIOs. A QIO must verify that the data it is currently receiving under the QIO program is comprehensive enough to re-use for the QE program and also must purchase any missing file types needed to conduct QE-related work. For more information on the process and cost associated with using already obtained Medicare FFS claims data under an existing DUA, please refer to the "Use of Medicare Data" page on the website.

Are pre-adjudicated claims data an acceptable source of other-payer claims data for the QE Program?

Pre-adjudicated claims data are an acceptable source of other-payer claims data, for combining with Medicare QE data and calculating measures for public reporting. However, pre-adjudicated claims data do not have final payment data; therefore, they are not sufficient for producing measures related to cost.

Are there minimum and maximum size requirements for the geographic areas for publishing public reports?

No, there are no restrictions on the geographic areas for which an entity can be certified to publish reports provided that the entity has access to a sufficient volume of claims data from other payer sources for the geographic area. However, note the following:

- Entities reporting on regions smaller than a state will need to purchase regional-level data for county cohorts, show they possess other payer sources of claims data, and meet the sample size requirements.
- Sample size requirements may be difficult to meet if the geographic area is too narrowly specified.
- If an entity intends to report on a geographic area that consists of several states, the entity must purchase data for each state separately, show they possess sufficient other payer sources of claims data for each state, and meet sample size requirements.
- The applicant must show that they have enough claims data information for the level of analysis. The level of analysis can be regional or provider level (e.g., individual physician, clinic, practice, or medical system).

Phase 2

Must the lead Qualified Entity (QE) in a QE collaborative (QE and contractual partners) assume responsibility for data integrity and security?

Yes, the lead QE must assume responsibility for data integrity and security for themselves and their contracting partners. While a QE's contractual partners may process the QE Medicare data, engage with providers in the corrections and appeals process, and produce public reports, under the CMS Data Use Agreement (CMS DUA), the lead QE is ultimately responsible to CMS for the integrity and security of the QE Medicare data.

How does an applicant demonstrate compliance with the data security requirements (Phase 2)?

To demonstrate compliance with data security (Phase 2), every contractor or organization within the QE that has access to beneficiary identifiable data must complete the QECP Data Security Workbook. The workbook is used to assess the QE's responses to moderate-level data security controls, which are organized across logical control families (e.g., risk assessment, access control, media protection, program management).

QEs must demonstrate full compliance with and implementation of the controls within the data security workbook. To attain compliance, QEs submit supporting documentation and self-attest that they meet the controls. QEs must also provide a rationale for each self-attestation. (For more information on documentation, please review the QECP Example Data Security Artifacts) contained within the Phase 2 toolkit).

The QECP is currently using the CMS Acceptable Risk Safeguards (ARS) for its data security and privacy assessments, which is based on NIST SP 800-53. The QECP will phase in the use of future ARS versions as they become publicly available.

Can my organization submit recent data security audits or assessments (e.g., ISO 270001, NIST 800-53, FedRAMP) as evidence for Data Security (Phase 2)?

Yes, the QECP allows QEs to submit recent data security assessments or audits as evidence for Data Security (Phase 2). Such audits may be accepted as evidence of compliance with ARS if they meet the following criteria:

- The scope of the audit clearly shows coverage of relevant controls;
- The assessment was conducted by an independent third party; and
- The assessment or audit was conducted within the last 365 days.

Examples of assessments include:

- Certification audit against ISO 27001

- Assessment and audit against HIPAA standards
- SSAE 16 Overview
- Statement on Standards for Attestation Engagements (SSAE) No. 16, Reporting on Controls at a Service Organization
- FedRAMP Certification: FedRAMP Certification must be accompanied by documentation for the services contracted (e.g., Infrastructure as a Service [IAAS], Platform as a Service [PAAS], or Software as a Service [SAAS])

For QEs with a private FedRAMP-certified data center, many of the Phase 2 data security controls should be covered by the data center's FedRAMP certification. For QEs contracting with a FedRAMP-approved cloud service provider, rather than operating a FedRAMP-certified data center, only a limited number of administrative, technical, and physical controls will be considered to be covered by the CSP's FedRAMP certification. QEs are responsible for submitting policies and protocols for controls not covered under this FedRAMP certification.

For further details and questions, please contact the QECP staff by email.

Is it recommended to pursue a data security certification such as National Institute of Standards and Technology (NIST) certification to help facilitate Phase 2 data security compliance?

Not necessarily. The QECP cannot recommend one approach for meeting the requirements for Data Security (Phase 2). The best approach will depend on an organization's infrastructure and resources.

For those applicants who have already undergone a NIST Certification and Accreditation process for compliance with Federal Information Processing Standards (FIPS) 200 and SP 800-53 at the moderate impact level, submission of the Certification and Accreditation document is sufficient evidence to demonstrate compliance with all elements of Phase 2.

Alternatively, for any applicants not currently possessing a NIST certification, the applicant must produce documentation of the systems and protocols that meet the same threshold as the security factors listed in FIPS 200 and SP 800-53 at the moderate impact level. For example, applicants must produce documentation describing the systems and protocols in place that show compliance with CMS' Acceptable Risk Safeguards (ARS) 2.0 requirements.

What information are QEs required to send to appealing providers during the corrections and appeals process for public reports?

During the corrections and appeals process, QEs must provide the measure name and description, methodology, and measure results to providers. Additionally, at the request of an appealing provider, QEs must also release the Medicare claims and/or beneficiary names to the provider with appropriate privacy and security protections. QEs may only provide the Medicare claims and/or beneficiary names relevant to the particular measure or measure results the provider is appealing.

The claims information provided by the QE to the appealing provider does not have to be fully identifiable. QEs must transmit claims information with the minimally necessary beneficiary

identifiers to providers. De-identified information (date of service, gender, age, service, etc.) meets the requirement of providing minimally necessary information to providers upon request.

Are QEs required by the QE Program to provide beneficiary information from the non-Medicare claims data used to calculate performance measures to providers, if they request it during the corrections and appeals process?

No, CMS does not provide guidance on how or if QEs should provide beneficiary information on their non-Medicare claims data to providers during the corrections and appeals process. However, CMS does encourage QEs to release their non-Medicare data during the corrections and appeals process whenever it is legally permitted by the terms of the agreement between the QE and the entity from which they received the data.

During corrections and appeals, must QEs require appealing providers to sign legal agreements, such as a business associate agreement, to receive requested Medicare claims data?

No, when transmitting requested claims data to an appealing provider, the QE must undertake the appropriate privacy and security protections (e.g., secure data transfer), but a legal agreement between the provider and QE is not required.

How much time do QEs have between a provider submitting a data request during corrections and appeals and the QE delivering the relevant data to the appealing provider?

This process does not have a set timeframe. However, QEs are expected to deliver the data to appealing providers in a reasonable amount of time. Each year, as part of the QE Annual Report, QEs must report to CMS the amount of time to acknowledge and respond to provider requests for error correction.

Additionally, after the corrections and appeals period, if a provider has a data or error correction request outstanding at the time the QE's performance reports become public, the QE must, if feasible, post publicly the name of the appealing provider and the category of the appeal request.

Do the corrections and appeals requirements for public reports apply to QEs that plan to report measures at the regional level and not the provider or provider group level?

No. A QE must have a provider corrections and appeals process in place except if it does not plan to report any measures at the provider or provider group level. If a QE believes that a provider corrections and appeals process is not required for its reporting, it must submit, during Phase 2 of the QECP application process, Request for Corrections and Appeals (Element 2.3), evidence that it has a process for ensuring that any published measure results could not be associated with a particular provider or provider group

The QE regulations refer to a downloadable NPI file where provider mailing addresses and other information can be found. Where can I find this information?

Information on the National Plan and Provider Enumeration System (sometimes referred to as the NPI downloadable file) may be found here. This CMS web page identifies the location of the NPI downloadable file, which includes provider name, mailing address, physical location, etc.

If a provider believes there is an error within the Medicare FFS claim during corrections and appeals, what should the provider do to reconcile the claim?

During the corrections and appeals process, if the provider believes there is an error with the Medicare FFS claims, the provider should follow-up with their Medicare Administrative Contractor (MAC) as necessary to reconcile/adjust the claim. The QE should move forward with their public reporting according to the program requirements. If the provider or supplier has a data or error correction request outstanding at the time the reports become public, the QE must denote the performance measure as "in dispute."

Phase 3

What evidence should be submitted to demonstrate the stakeholder consultation approval process for proposed alternative measures? Can you give some examples of the stakeholders in the community that should be involved?

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

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

Stakeholders must include a valid cross-representation of providers, payers, employers, and consumers within the QE's community and public reporting area.

Once an entity is certified as a QE, the QECP team is available to assess or discuss proposed evidence for a QE's stakeholder consultation process well in advance of its Phase 3 submission.

QEs interested in requesting this assistance, use the Contact Form to contact your Program Manager.

The QE regulations state that information on individual providers can only be publically released in aggregate form. What exactly does this mean? Can you provide an example?

This excerpt of the QE regulations means that all results calculated for providers and suppliers must be aggregated and reported at a level higher than the patient level. Information on individual beneficiaries may NOT be disclosed. No individual patient should ever be placed at risk for identification based on results presented in a public report.

Example: When a provider's influenza immunization rate for CY 2010 is reported to the public, the result should be expressed following the specifications of the standard measure (which includes a minimum sample size). For example, 80 percent of Dr. Smith's patients received an influenza immunization during CY 2010. Releasing a list of patients (for example, those patients with or without an influenza immunization) in a public report, or in any form in which someone could identify a patient, is strictly prohibited.

What are CMS's guidelines for cell suppression in public measure reporting?

A QE may display a result for an aggregate measure only if there are at least 11 individuals in the denominator. In addition, no percentages or other mathematical formulas may be used if they result in the display of a cell size of 11 or less. For example, a QE is permitted to display an aggregate measure for a given provider that has:

- 35 Medicare beneficiaries and 3 commercial members in the denominator, or
- 6 Medicare beneficiaries and 10 commercial members in the denominator.

What are CMS's guidelines for Medicare-specific public reporting?

QEs may not calculate and report measure results based only on Medicare data (this also applies to cases where the Medicare FFS data obtained from CMS is combined with Medicare Advantage data). However, a QE may drill down into a calculated measure and report results based only on Medicare data. The QE must comply with all cell suppression guidelines in reporting Medicare-specific measure results (i.e., there must be at least 11 Medicare beneficiaries in the measure denominator).

For example:

- It would be acceptable for a QE to report Provider A's result on a measure that contained 15 Medicare beneficiaries, 10 commercial members, and 12 Medicaid beneficiaries and then to drill down and report product-specific results for commercial products, Medicaid, and Medicare. This is permissible because there are at least 11 Medicare beneficiaries.
- It would be acceptable for a QE to report Provider A's results on a measure that contained 8 Medicare beneficiaries, 10 commercial members, and 12 Medicaid beneficiaries and then to drill down and report a product-specific result ONLY for commercial products. This is permissible

because the Medicare data are still combined with the Medicaid data, so the user cannot work back to the Medicare figure.

- It would be unacceptable for a QE to drill down and report Provider A's results for a measure for commercial products, Medicaid, and Medicare if there were 8 Medicare beneficiaries, 10 commercial members, and 12 Medicaid beneficiaries in the measure. This is not permissible, because there must be at least 11 Medicare beneficiaries in the aggregate measure if a QE wants to report by product line.

What are CMS's guidelines for comparative reporting?

QEs may not calculate and report measure results based only on Medicare data (this also applies to cases where the Medicare FFS data obtained from CMS is combined with Medicare Advantage data). However, a QE may drill down into a calculated measure and report results based only on Medicare data. The QE must comply with all cell suppression guidelines in reporting Medicare-specific measure results (i.e., there must be at least 11 Medicare beneficiaries in the measure denominator). For instance, it would not be permissible for a QE to calculate a hip-replacement measure using only commercial data and then compare it to the hip-replacement measure calculated using only Medicare data.

QE Program Information

What is the Qualified Entity Medicare Data Sharing Program?

The Qualified Entity (QE) program facilitates the creation of actionable performance reports that cover all, or most, of a provider's practice. Under the QE program, CMS is authorized to disclose standardized extracts of Medicare Parts A and B claims data and Part D prescription drug event data to "qualified entities" (QEs). QEs must combine the Medicare data with claims data from other sources to create public reports that evaluate provider performance. QEs are also permitted to use the Medicare data to create non-public analyses and provide or sell such analyses to authorized users. In addition, QEs may provide or sell combined data, or provide Medicare claims data alone at no cost, to certain authorized users.

For more information, please see the final rule establishing the program and the final rule modifying the program.

What is the Qualified Entity Certification Program?

The Qualified Entity Certification Program (QECP) is the certification arm of the Qualified Entity Medicare Data Sharing Program. The purpose of the QECP is to evaluate and certify an entity's ability to serve as a qualified entity (QE). Once certified, QEs are eligible to receive standardized extracts of Medicare Parts A and B claims data and Part D prescription drug event data for the purpose of evaluating the performance of providers. QEs are also permitted to create non-public analyses and provide or sell such analyses to authorized users. In addition, QEs may provide or sell combined data, or provide Medicare claims data alone at no cost, to certain authorized users. QEs must comply with all QECP requirements described in the QECP Program Guide, including, but not limited to, the QECP phased minimum requirements review and public reporting. The QE Medicare Data Sharing Program Regulations establish the criteria that entities must satisfy to obtain QE certification.

What are the regulations that established the QE Program?

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. The QE regulations (42 CFR §401.701–401.722) establish the requirements of the QECP and the QE CBEC Program.

Standard and Alternative Measures

What types of measures can QEs calculate for public reports using the Medicare claims data?

For public reports, QEs are required to use standard measures or approved alternative measures for evaluating the performance of providers and suppliers. Standardized and well-specified measures that follow tested methodologies allow results to be compared credibly across providers and organizations. All measures must include claims data from other payer sources; measures using only the Medicare data are strictly prohibited.

Standard measures are claims-based measures that can be calculated in full or in part from claims data from other sources and the standardized extracts of Medicare Parts A and B claims data and Part D prescription drug event (PDE) data. They include all performance measure types, such as quality measures (structure, process, and outcomes measures), resource use measures, efficiency measures, and composite measures. A standard measure must fall into one of the following categories: the measure is endorsed by the entity with a contract under Section 1890(a) of the Social Security Act (currently the National Quality Forum); the measure is currently being used in a CMS program that includes quality measurement; or the measure is endorsed by a CMS-approved QE Consensus-Based Entity (CBE).

Alternative measures are non-standard claims-based measures, 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 PDE data, that have 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. Alternative measures will be accepted either through the notice-and-comment rulemaking process or through a stakeholder consultation approval process in which entities demonstrate consultation and agreement with appropriate stakeholders in the community. QECP alternative measures approved under the stakeholder consultation approval process may only be used by the QE that submitted the measure to CMS for consideration. QECP alternative measures submitted through the notice-and-comment rulemaking process may be used by any QE. Currently, no measures have been submitted through the notice-and-comment rulemaking process

Please keep in mind that the QECP standard and alternative measures lists are dynamic because the measures continually undergo review for endorsement. The QECP team will update the standard and alternative measures lists twice per year, in January and July, but it is ultimately the applicant's responsibility to obtain the most recent information.

If we find it difficult to use an NQF measure specification exactly as it is defined, and modify it only slightly, will such a measure be considered standard for the QECP Program?

If a measure does not follow the exact specification as the NQF-endorsed measure, it will be considered an alternative measure. Entities may submit alternative measures for approval if the entity is able to demonstrate stakeholder consultation and approval of the deviation from the standard measure specification.

Can composite measures be used for public performance reporting? Are composite measures considered "standard" measures if they are entirely created from NQF-endorsed measures?

Yes, composite measures may be used as part of a QE's public performance reporting. However, every composite measure is considered an alternative measure unless the composite measure itself is NQF-endorsed, used by a CMS program, or endorsed by a QE CBE. Composite measures are considered alternative measures even if they composite, or combine, individual NQF-endorsed standard measures.

Are measures from a retired CMS quality program (that are not NQF-endorsed) considered standard measures?

No, measures from retired CMS quality programs that are not NQF-endorsed are not considered standard measures and must be submitted as alternative measures.

Uses of Medicare Data

Will the release of QE Medicare data mean that CMS will no longer release data for research purposes?

No, CMS will continue to release data for research purposes. For information on all CMS data release programs, visit ResDAC's "CMS Data" page: http://www.resdac.org/cms-data.

How can Medicare data be used under the QE Program?

Qualified entities (QEs) are required to use the QE Medicare data, combined with other sources of claims data, to create public provider performance reports at least once annually. In addition, QEs may use the QE Medicare data, combined with other sources of claims data* to conduct non-public analyses and to provide or sell those analyses to authorized users. QEs may also provide or sell the combined data or provide Medicare-only claims data at no cost to certain authorized users (providers, suppliers, hospital associations, and medical societies) for non-public use.

For more information on public reporting requirements, please review the materials included in the "Phase 3" page on the website. For more information on permissible uses of QE Medicare data under the QE program, see the other FAQs and materials included on this "Uses of Medicare Data" page.

*For qualified clinical data registries (QCDRs) acting as quasi qualified entities (quasi QEs), combined data refers to CMS claims data provided through the QE Program, combined with

clinical data or a subset of clinical data. The Application Overview page contains additional information on quasi QEs.

Can my organization use the QE Medicare data to conduct research?

QEs may request to re-use the QE Medicare data they received under the QE program for research purposes. QEs that are interested in using the Medicare claims data for research purposes must go through the research request process and obtain a new data use agreement (DUA) with CMS. Additional information on the research request process can be found at http://www.resdac.org/cms-data/request/research-identifiable-files.

Can my organization provide or sell data and analyses without releasing public performance reports?

No, QEs must comply with all QECP program requirements, including the requirement to release at least one public report annually on the performance of providers. Refer to the QECP Program Guide for complete information on QE program requirements.

Who is an authorized user?

An authorized user is a third party (and/or its contractors or business associates) to which a QE provides or sells data or analyses. Authorized users are limited to the following types of entities:

- A provider – 42 CFR §401.703(b)
- A supplier – 42 CFR §401.703(c)
- A medical society – 42 CFR §401.703(m)
- A hospital association – 42 CFR §401.703(n)
- An employer – 42 CFR §401.703(k)
- A health issuance insurer – 42 CFR §401.703(l)
- A healthcare provider and/or supplier association – 42 CFR §401.703(o)
- A state entity – 42 CFR §401.703(p)
- A federal agency

Are there restrictions on the types of data or analyses that a QE can provide or sell to an authorized user?

Yes, the table below summarizes the types of analyses/data that a qualified entity may provide or sell to an authorized user.

Additional Uses of the QE Medicare Data: Summary of Authorized Users

Authorized Users	De-identified Non-Public Analyses*	De-identified Data*	Patient-Identifiable^ Data and/or Non-Public Analyses
Providers	X	X	X
Suppliers	X	X	X
Medical Societies	X	X	
Hospital Associations	X	X	
Employers	X		
Health Insurance Issuers	X		
Healthcare Provider or Supplier Associations	X		
State Agencies	X		
Federal Agencies	X		

*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/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html.

*Authorized users of identifiable data and analyses include only providers and suppliers with a patient relationship. A patient means an individual who has visited the provider or supplier for a face-to-face or telehealth appointment at least once in the past 24 months.

Can QEs provide or sell combined data to researchers?

No. The Medicare Access and CHIP Reauthorization Act (MACRA) only permits QEs to provide or sell combined data or provide Medicare data at no cost to providers, suppliers, medical

societies, and hospital associations. Therefore, QEs are not permitted to provide or sell combined data or provide Medicare data at no cost to researchers.

While the QE regulations at 42 CFR Part 401, Subpart G, govern the release of Medicare data and combined data, these regulations do not impact the release of commercial-only data.

What is the process and cost for a QE that wants to re-use data obtained through the QE program for other purposes, such as research?

A QE that wants to re-use data it received under the QE program for another purpose must submit a new DUA that will go through the existing process for research and state agencies, including CMS Privacy Board review and approval. The QE will not be required to pay for the data again, but it will be required to pay the $2,000 administrative fee. More information on permissible uses of QE program data can be found in the QE Public Reporting Tip Sheet and Uses of QE Medicare Data Tip Sheet.

Are there contractual agreements that need to be in place prior to providing or selling analyses or data?

Yes, a QE must enter into a QE DUA or a non-public analyses agreement with an authorized user prior to providing or selling data or analyses to that authorized user.

A QE DUA must be in place as a pre-condition of providing or selling any QE data (including combined or Medicare-only data, whether beneficiary-identifiable or de-identified) or non-public analyses containing protected health information (PHI). The required provisions for a QE DUA can be found at 42 CFR §401.713(d).

A non-public analyses agreement must be in place before a QE may provide or sell beneficiary de-identified non-public analyses to an authorized user. The required provisions for a non-public analyses agreement can be found at 42 CFR §401.716(C).

It is the QE's responsibility to develop and execute the legally binding agreement with the authorized user prior to providing or selling data or analyses. The QE must ensure that the required provisions are included in the QE DUA or non-public analyses agreement.

For non-public analyses, must QEs use only standard and alternative measures?

No, QEs can work directly with the authorized users that are receiving or purchasing the non-public analyses to determine the measures that will be included. QEs are not restricted to using only standard and approved alternative measures for non-public analyses.

Are there any restrictions on the use of the publicly reported results included in QEs' provider performance reports?

No. The QE regulations do not impose restrictions on the uses of the publicly reported results (the numerical values of the measures published). Publicly reported results can be used by any party,

including the qualified entity, for activities such as internal analyses, pay-for-performance initiatives, or provider tiering. After the QE has transformed the data into publicly reported information, other than the statutory requirement that the reports be shared with providers and the public, CMS does not assert ownership or control over additional uses that the QE may make of the publicly reported information.

The QE regulations stipulate that "publicly reported results could be used for internal analyses, pay-for-performance initiatives, or provider tiering." Can you provide an example of provider tiering?

Provider tiering is interpreted as a method for aggregating providers according to some predetermined criteria, for example, Tier A: Primary Care Physicians (PCPs) Scoring Above Average on Quality; Tier B: PCPs Scoring Average on Quality; Tier C: PCPs Scoring Below Average on Quality.

Can the QE Medicare data be used to validate standard measures used in public reporting? What is the difference between validating a measure and measure testing?

Yes, the QE Medicare data may be used to validate standard measures that the QE intends to publically report under the QECP. However, every attempt must be made by QEs to use the QE Medicare data only to calculate measures that have previously demonstrated statistical validity. For measures considered standard under the QE program, if a QE is unsure whether a measure will be statistically valid when applied to the combined data, the QE is permitted to combine the Medicare data with the other payer claims data and run the measure on these combined data to determine validity.

If the measure passes the validity checks, the QE must include it in its public performance report(s); thus, the measure must be added to the QE's Phase 3 Measure Information Workbook and submitted to the QECP team for review at the time of the Phase 3 minimum requirements review, or at least 30 or 60 days (depending on the measure type) before its intended confidential release to providers for the corrections and appeal process. If the measure does not pass the validity checks, it should not be added to the Measure Information Workbook; however, the QE must internally document that the Medicare data were accessed (and for which measure), but were not used, and must have this documentation available if the QECP team conducts a review as part of Ongoing Program Administration (OPA). The QE must report the list of measures that did not pass validity, together with a brief rationale, as part of its required QE Annual Report Workbook submission.

Measure testing is defined as using QE Medicare data to calculate standard or alternative measures without reasonable confidence that the measure will pass statistical validity testing. Measure testing is not permitted under the QE program for public performance reports.

What is the process and cost for a QE that has already obtained Medicare FFS claims data under an existing DUA and intends to use the data for the QE program?

A QE that has obtained Medicare FFS claims data under an existing DUA and intends to use only those data for its work as a QE will be required to comply with the four phases of the QE program,

including submitting a DUA for the QE program. However, the QE will not be required to pay for the data or to pay the $2,000 administrative fee for DUA processing.

A QE that already has Medicare FFS claims data under an existing DUA and intends to use the data for the QE program and that requests additional Medicare FFS claims data for its work as a QE will also need to comply with all four phases of the QE program, including submitting a DUA for the QE program. The QE will not be required to pay for existing data or to pay the $2,000 administrative fee for processing the DUA; however, the QE will be required to pay for any new data requested.

This policy is consistent with existing CMS data re-use and QE policies. According to the CMS data re-use policy for research and state agencies, an entity that has Medicare FFS claims data and wants to re-use those data must submit a new DUA, but is not required to pay for the data again. Although researchers and state agencies are required to pay a $2,000 administrative fee for DUA processing, QEs will not be required to pay this fee, because CMS DUAs are not reviewed and approved by the CMS Privacy Board. Instead, QEs participate in a comprehensive review in order to participate in the QE program.