SIM Learning Event: Claims and Clinical Data Aggregation – The Role of Qualified Entities (QEs)

Patricia MacTaggart, ONC
Kari Gaare, CMS
Allison Oelschlaeger, CMS

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Agenda

- Introductions:
  - Patricia MacTaggart, ONC
  - Presenters: Kari Gaare and Allison Oelschlaeger, CMS

- Framing the Discussion: Patricia MacTaggart, ONC

- State Access to CMS Data: Kari Gaare and Allison Oelschlaeger, CMS
All-Payers Claims and Non-Claims Clinical Information Integration

• Multiple Ways to Accomplish
  • Leveraging current APCDs: Previous discussion
  • Leveraging Medicare Qualified Entities: Today discussion
  • Leveraging other State efforts: Possible future presentations
  • Forming Something New: APCD and/or Other
SIM Learning Event: Access to CMS Data

Office of Enterprise Data & Analytics
July 26, 2016
1. State Agency Research Data Requests
   - For states interested in conducting research using Medicare data
   - State agency requesting the data may further disseminate the data to other agencies in the state who are conducting research

2. Data for Care Coordination and Program Integrity Activities for Medicare-Medicaid Enrollees
   - For states interested in coordinating care, improving quality, and controlling costs for dual eligible beneficiaries
   - States can only receive Medicare data for Medicare beneficiaries enrolled in the state Medicaid program

3. Qualified Entity (QE) Program
The QE Program was established by Section 10332 of ACA and authorizes CMS to disclose Medicare claims data to approved entities ("qualified entities") for provider performance reporting:

- QEs must combine the Medicare claims data with claims data from other sources.
- QEs must publicly report on provider performance after allowing time for providers to confidentially review their results and request correction of errors.

The QE Program changed the performance measurement landscape by facilitating the creation of actionable performance reports that cover all/most of a providers’ practice.
Helping Consumers Choose Providers Based on Quality and Cost

**PAST**
- Insurance Companies
- Medicare?

**PRESENT**
- Insurance Companies
- Medicare?
- Qualified Entity
- Comprehensive
- Consistent
- Fair
- Actionable
Current QEs

National QEs:
- HCCI
- Amino
- OptumLabs
- FAIR Health
Who Can Become a QE?

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

- Have access to claims data from other sources to combine with the Medicare data*
- Have strong systems to ensure that the data are secure and protected
- Have experience in a variety of tasks related to the calculation and reporting of performance measures, including: combining claims data from different payers, designing performance reports, sharing performance reports with the public, working with providers and suppliers regarding requests for error correction, and ensuring the privacy and security of data

CMS has not established any limitations on the type of organization that can become a QE
MACRA Changes to the QE Program

- ACA provisions stated that QEs could only use Medicare data to create public reports that evaluate the performance of providers.
- Section 105 of MACRA provides for additional uses of the Medicare data:
  - Allows QEs to provide or sell analyses for non-public use.
  - Allows QEs to provide or sell the combined Medicare and other payer data (or provide the Medicare data at no cost) to certain types of users.
- Section 105 of MACRA also includes additional privacy and security requirements and expands the annual reporting requirements for QEs.
- Final rule was published July 7, 2016 and will be effective on September 6, 2016.
Overview: Permissible Uses of QE Medicare Data

Data Use

1. Provide or sell beneficiary de-identified non-public analyses
2. Provide or sell beneficiary de-identified combined data or provide beneficiary de-identified Medicare data at no cost
3. Provide or sell patient-identifiable combined data or non-public analyses or provide patient-identifiable Medicare data at no cost

For Use By

- Providers and suppliers
- Employers
- Health Insurance issuers
- Medical societies
- Hospital associations
- Healthcare provider or supplier associations
- State entities
- Federal agencies
- Providers and suppliers
- Medical societies
- Hospital associations
- Providers and suppliers

Required Contractual Agreement

- Non-Public Analyses Agreement
- QE Data Use Agreement
- QE Data Use Agreement

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1. A corrections and appeals process is required for public reports and non-public analyses that contain information that individually identifies a provider or supplier other than the provider or supplier receiving the analysis.

2. Public provider performance reports must be released within one year from receipt of QE Medicare data and annually thereafter.

3. Patient-identifiable data and non-public analyses may only contain identifiable information on beneficiaries with whom the provider 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.
De-Identified Non-Public Analyses

QEs may:

- Use the combined data to create de-identified non-public analyses; and
- Provide or sell the de-identified non-public analyses to authorized users

QEs are permitted to provide or sell de-identified non-public analyses to the following authorized users, including their contractors and business associates:

- Providers and suppliers, Employers, Health insurance issuers, Medical Societies, State entities, Hospital associations, Healthcare provider or supplier associations, Federal agencies

Combined Data - at a minimum, a set of CMS claims data provided under the QE program combined with claims data, or a subset of claims data, from at least one other claims data source
De-Identified Non-Public Analyses, continued

- Authorized users may **not** use the 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 healthcare system
  - Effectuating or seeking opportunities to effectuate fraud and/or abuse in the healthcare system

- QE's must enter into a contractually binding non-public analyses agreement with an authorized user prior to providing or selling de-identified non-public analyses.

- Corrections and Appeals Process
De-Identified Data

● QEs may:
  ○ Provide de-identified combined data or de-identified Medicare-only data at no cost
  ○ Sell de-identified combined data

● QEs are permitted to provide or sell de-identified data only to the following authorized users, including their contractors and business associates:
  ○ Providers and suppliers
  ○ Medical Societies
  ○ Hospital Associations
De-identified Data, continued

- Authorized users may use the de-identified data only in a manner that a HIPAA-covered entity could under the following provisions:
  - Activities falling under paragraph (1) and paragraph (2) of the definition of “health care operations” under 45 CFR 164.501:
    - Conducting quality improvement, care coordination, patient-safety, and population-based activities
    - Evaluating practitioner and provider performance and conducting training and 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)
- QEs must enter into a contractually binding QE Data Use Agreement (QE DUA) with an authorized user prior to providing or selling any de-identified combined data or providing de-identified Medicare-only data.
Patient Identifiable Data and Non-Public Analyses

QEs:
- Provide identifiable combined data, identifiable Medicare-only data,* or identifiable non-public analyses to authorized users at no cost; or
- Sell identifiable combined data or identifiable non-public analyses to authorized users

QEs are only permitted to provide or sell data or analyses that individually identify a beneficiary to a provider or supplier with whom the identified beneficiary has a current 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
Patient Identifiable Data and Non-Public Analyses, con't.

● Authorized users may use the identifiable data and analyses only in a manner that a HIPAA-covered entity could under the following provisions:
  ○ Activities falling under paragraph (1) and paragraph (2) of the definition of “health care operations” under 45 CFR 164.501:
    ● Conducting quality improvement, care coordination, patient-safety, and population-based activities
    ● Evaluating practitioner and provider performance and conducting training and 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)

● QEs must enter into a contractually binding QE DUA with an authorized user prior to providing or selling any patient identifiable combined data, Medicare-care only data, or non-public analyses
## Summary of Authorized Users

<table>
<thead>
<tr>
<th>Authorized Users</th>
<th>De-identified Non-Public Analyses</th>
<th>De-identified Data</th>
<th>Patient-Identifiable Data and/or Non-Public Analyses</th>
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<td>Supplier Associations</td>
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<td>Federal Agencies</td>
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Contractually Binding Agreements

- The two new types of agreements include:
  - Non-Public Analyses agreement: A contractually binding agreement between the QE and an authorized user that is a precondition to providing or selling beneficiary de-identified non-public analyses.
  - QE DUA: A contractually binding agreement between the QE and an authorized user that is a precondition of:
    - Selling or disclosing any combined data or any Medicare claims data (or any beneficiary-identifiable derivative data of either type)
    - Selling or disclosing non-public analyses that include individually identifiable beneficiary data

- Required Provisions include:
  - Use of analyses or data, Re-disclosure, Linking/re-identification, Violations, Privacy and Security Requirements
Reporting Requirements and Violations

- Additional Annual Reporting Requirements

- Assessments DUA violations
  - CMS may impose an assessment on the QE for a violation of a CMS DUA or QE DUA
  - CMS will calculate the amount of the assessment of up $100 per individual Medicare beneficiary whose data were implicated in the violation
Resources

- Recent **QE Final Rule**

- Please visit:
  - [Qualified Entity Certification Program website](#) for additional information about the qualified entity program and email support@qemedicaredata.org with any questions
  - [Research Data Assistance Center (ResDAC) website](#) for additional information about the state agency research request process
Open Discussion

Patricia Mactaggart: Patricia.Mactaggart@hhs.gov
Kari Gaare: Kari.Gaare@cms.hhs.gov
Allison Oelschlaeger: Allison.Oelschlaeger@gms.hhs.gov