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Summary of Final Rule on MACRA Amendments to the Qualified Entity program

July 8, 2016

On July 7, 2016, CMS published final regulations implementing the non-public use provisions for the Qualified Entity program. The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 expanded how Qualified Entities (QEs) could use and disclose data under the program, beyond the public performance reports originally authorized under the Affordable Care Act. Under section 105 of MACRA, Qualified Entities will be allowed to:

1. **Use combined data to conduct non-public analyses and provide or sell these analyses to authorized users for non-public use**. MACRA defines authorized users to include (1) providers, (2) suppliers, (3) employers, (4) health insurance issuers that provide the QE with data, (5) medical societies or hospital associations, and (6) other entities that are approved by the Secretary.

2. **Provide or sell the combined data, or provide the Medicare claims data alone at no cost, to a subset of authorized users** – i.e., providers, suppliers, hospital associations and medical societies.

Through this rulemaking, CMS implements these provisions through amendments to 42 C.F.R. Part 401, subpart G, "Availability of Medicare Data for Performance Measurement." These final regulations do not change existing requirements regarding eligibility to become a QE or processes and standards surrounding public performance reports.

NRHI submitted extensive comments to CMS on these provisions, in advance of the proposed rulemaking and again in response to the proposed rulemaking. NRHI was one of 53 organizations that submitted comments on the proposal. In the final rule, CMS addressed each of NRHI's comments, and accepted many, but not all of its recommendations.

The chart that follows summarizes the core provisions on which NRHI offered recommendations, and compares the proposed and final regulations.

Provision	Proposed Rule	Final Rule	Discussion
Authorized users	An authorized user is a third party to whom/which the QE provides or sells data. Authorized users are limited to the following entities: (1) Provider (2) Supplier (3) Medical society (4) Hospital association (5) Employer (6) Health insurance issuer (7) Healthcare provider and/or supplier association (8) State agency	CMS added one new authorized user: federal agencies.	NRHI had recommended that RHICs and academic institutions and researchers be added to the list of authorized users. It also urged CMS to create a process separate from notice and comment rulemaking that would allow QEs to seek approval for additional authorized user types. CMS said commenters had offered a wide ranging list of suggested additions to the definition of an authorized user but that CMS must maintain a "carefully curated list of authorized users to prevent the monitoring of the QE program from becoming too cumbersome." Perhaps showing its lack of understanding of RHICs, the Agency also stated that "many of the other suggested authorized users do not represent well-defined groups." CMS also declined to establish a separate process to add new types of authorized users to the list, meaning that CMS will amend the list only through notice and comment rulemaking.

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Subcontractors	*No provision*	CMS is expanding the definition of an authorized user to include third party users *and their contractors* that need analyses or data to carry out work on behalf of the authorized user.	NRHI recommended that entities that are allowed to act on behalf of their subparts (e.g., hospital networks, Accountable Care Organizations, coalitions) be allowed to receive analytics and data directly from CMS. CMS agreed with the recommendation and stated that organizations acting under a contract with an authorized user can receive data or analyses on behalf of that authorized user. CMS also noted that QEs would be liable for the actions of these subcontractors.
Combined data	Combined data means a set of CMS claims data combined with claims data (or a subset of claims data) from at least one other source.	No change	NRHI had asked CMS to clarify how the requirement of a "combined data set" practically impacted the ability to study Medicare-only populations, and to allow QEs to use combined data sets to drill down on specific populations, including the Medicare fee-for-service population. Consistent with NRHI's comments, CMS offered an important clarification on the ability to drill down on Medicare-only data. CMS provided the following clarification in response to comments:
			"the requirement to use combined data does not prevent QEs from providing or selling analyses that allow the authorized

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			user to drill down by payer type to Medicare-only results. For example, a qualified entity 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 presents scores for each of these measures by payer type (including a Medicare fee-for-service category)."
Health insurance issuer data contribution thresholds	A QE may only provider or sell a non-public analysis to a health insurance issuer after the issuer has provided the QE with claims data that represents a majority of the issuer's covered lives for the time period and geographic region covered by the analysis.	CMS made only minor modifications to this provision. The revised regulation states that a QE may only provide or sell a non-public analysis to a health insurance issuer after the issuer (or its business associate) has provided the QE with claims data that represents a majority of the issuer's covered lives for the time period and geographic region covered by the analysis. CMS also added a definition of "covered lives" that incorporates Internal Revenue Service (IRS) regulations. Under these	NRHI recommended that CMS give QEs discretion to provide or sell analyses to health insurance issuers who have made a good faith commitment to providing the QE with claims data that represents a majority of the health insurance issuer's covered lives. CMS declined to alter its original proposal, stating that a more permissive policy could reduce the incentives for issuers to share data with the QE and could result in unequal standards across QEs.

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		regulations, there are 4 methods of calculating the average number of lives covered under a specified health policy: (1) the actual count method; (2) the snapshot method; (3) the member months method; and (4) the state form method.	
Patient relationship	Non-public analyses and data sets that contain information that individually identifies a beneficiary may only be disclosed to a provider or supplier if (a) the beneficiaries identified are those with whom the provider or supplier has a *patient relationship*, and (b) a Data Use Agreement (DUA) is in place between the QE and the user. A patient relationship exists where an individual has visited the provider or supplier for a face-to-face or telehealth appointment at least once in the past 12 months.	CMS amended the definition of a patient relationship to include patients that have visited their provider or supplier at least once in the last 24 months.	

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Provider requests for error correction	QEs must comply with the same error and correction process and timelines as required for public performance reporting when sharing a non-public analysis that individually identifies a provider or supplier that is not the requestor of the analysis.	CMS creates an "opt-in" process whereby QEs must put providers and suppliers on notice that they will be identified in a non-public analysis, and allow them the opportunity to request a review. QEs must provide the notice at least 65 calendar days prior to disclosing the analysis to the requesting authorized user. The 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 users receiving the analysis, and the date on which the QE will release the analysis. If a provider or supplier "opts-in" to the review, the QE must adhere to the review and correction process as is required for public reports.	CMS accepted some, but not all, of NRHI's recommendations. • CMS did create an alternative process that provides notice but does not require QEs to share the full analysis or data unless requested. • CMS declined to narrow the situations where QEs would need to comply with the review and correction process (e.g., where analyses identified group practice but not individual physicians; where physicians are employees/independent contractors of the authorized user requesting the report) • CMS declined to limit the number of opportunities providers and suppliers would have to review the same underlying data.

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Providing Medicare Claims Data at No Cost	QEs can provide Medicare data at no cost to providers, suppliers, medical societies, and hospital associations.	No change	CMS acknowledged that there are costs associated with providing Medicare data to authorized users, but stated that the paperwork and processing costs associated with filling requests are an integral part of the "provision" of the data, which must be done at no cost per MACRA. CMS noted that QEs are not obligated to offer free Medicare data to authorized users, and can instead choose to sell combined data sets, or not sell any data at all.
Qualified Clinical Data Registries (QCDRs)	*No provision*	CMS modifies the regulations to allow QCDRs to serve as "quasi-qualified entities," provided that they meet all of the requirements outlined in the QE regulations (except for the requirement that they demonstrate access to claims data from other sources). With respect to QCDRs, "combined data" is defined to mean Medicare claims data combined with clinical data or a subset of clinical data.	NRHI, along with several other commenters, had recommended that CMS establish a new pathway for QCDRs to obtain Medicare data that is better aligned with the QE program. CMS recognized that the research request (ResDAC) pathway was not always consistent with types of analyses QCDRs envision conducting using the CMS, and therefore modified its proposal to allow QCDRs to serve as "quasi-qualified entities."
Effective date		September 7, 2016	

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Security issues	*No provision*	*No provision*	NRHI had requested that CMS provide additional technical support during the security phase of the application process. CMS acknowledged NRHI's request for more technical support on the security phase of the application process, and stated that it would take the comments into consideration as it looked for ways to improve the program.