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Comments on CMS-0042-NC
Submitted by: Theresa Hush, CEO
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Thank you for the opportunity to respond to this RFI. Roji Health Intelligence began operations in 2002, with a mission to help providers succeed in achieving higher quality health care at affordable cost. We provide technology-based services to our clients to measure and improve the quality of care delivered, and to reign in costs. We are a Qualified Registry for MIPS and APP quality reporting, reporting both eCQMs and CQMs. The Roji Clinical Data Registry is certified by ONC for its ability to collect QRDA I data electronically and convert to eCQMs for quality reporting. We also provide cost control tools to our provider clients, using Roji's technology to create episodes of care to track outcomes and costs in chronic disease, treatment episodes, and procedures. We help clients participate in CMS payment models, such as ACOs and the Enhancing Oncology Model.

Our comments below reflect more than two decades of experience in clinical and claims data aggregation, health care technology, and data-driven strategies for Value Based Care, working with our clients from the board room down to individual clinicians and staff. We have three particular areas of commentary:

(1) Data held by business associates of clinical entities and ONC-certified entities, such as Roji Health Intelligence and other technology vendors, and whether it is complete and accurate for provision to patients directly by the business associate;
(2) Patient identity and security issues that must be resolved prior to sharing any provider EHR or analytics to patients from third party business associates; and
(3) Quality.

Data Held by Business Associates / Technology Companies like Roji Health Intelligence

As a Qualified Registry, Roji Health Intelligence aggregates data electronically from our client providers. These are submitted either as QRDA I files, flat files, or other types of data feeds to our secure FTP server, based on client user credentials, at least monthly but often more frequently. A unique aspect of the Roji data collection is that we do not depend on G-Codes or similar data fields to meet quality measure data, but collect clinical values such as hemoglobin A1c, blood pressure, left ventricular ejection fraction and many other values throughout the year.

We have found that while the quality of data over the last two decades has vastly improved, there are still many issues to resolve before it be considered complete and accurate, and any derivative uses – such as analytics and risk assessments – are also accurate.

We commend CMS's plan to develop a patient-centric system to facilitate patient education and decision-making and improve or streamline medical services to the patient. We are in total agreement that provider and payer systems with patient health data must be able to provide such information to the patient. Quality reporting and status of patients' quality measure results, for example, could be part of the plan of this ecosystem.

However, we do not believe that it is in the interests of patients to provide data directly from other organizations beyond their clinical providers and payers. Analytics, risk assessments, quality performance, episodes of care, and suggested interventions for patients that Roji Health Intelligence provides to its client providers cannot be deemed true and complete for the following reasons:

- Quality Measure Performance. The data may be incomplete, reflecting missing clinical values, codes and procedures because of EHR setup issues. For example, our provider clients with specialty services often have specialty templates that store data in separate templates. For quality reporting, we frequently need to work with clients to obtain special separate reports to add data.
- Clinical Episodes and Costs. Roji Episodes of Care examine status of patient outcomes and identify variations in costs as well as expected clinical processes. We provide this data for use by providers in creating improvement programs and engagement of providers in cost. This data needs clinical review and validation, and peer review of results.
- Cost of Care. The most critical element to achieving this goal is comprehensive and accurate data, with results that can be drilled down to identify the unique patient and data elements associated with each outcome. For that reason, CMS and other payers should make claims data available for providers, even if they are not participating in a payment model. This data is critical for value-based care networks to effectively manage their populations, understand comorbidities of patients, and improve quality and costs. It is impossible to identify trends related to excess costs our poor downstream outcomes without knowing what happens outside of a provider's view (E.1.TD-2.a).

Therefore, CMS should absolutely endorse non-CMS data sources and networks (E.4.TD-12). Any attempts at creating multi-payer initiatives will require the support of entities who can create patient profiles using disparate sources of data. Patients move in and out of coverage from various payers, and transition between various providers. Independent and vetted third party data aggregation intermediaries will be critical to population management, and for measuring quality and cost. This also illustrates why we support an All-Payer standard: Even if there is proprietary information related to costs, providers should be able to see their patients' claims data with standardized (e.g. CMS fee schedule) charges to identify utilization and cost variation. This certification could also come through an independent entity to ascertain proficiency with open, standards-based, publicly available APIs (2.TD-14).

Data Security and Patient Identification Processes

Data security is paramount, as health data has been heavily targeted by hackers seeking ransom or use of the data for illegal activities. For these reasons, we strongly suggest that patients should be able to obtain their data exclusively through their providers' patient portal, or downloaded to qualified applications from their providers, or from a wearable that the patient has purchased or has been provided by their providers. We strongly oppose direct access to patient data from business associate vendors, or Qualified Registry or QCDR, for these reasons:

- The patient has not signed up for these services, as they are provided only through a contract with the provider entity.
- The business associate does not have the capability to verify, identify, or confirm any patient identities. To allow patient access creates a risk for a breach of patient information, as these data companies are not now set up to deal with the public.
- Even in cases where an identity could be confirmed, there are potential risks (3.c). For example, access to proprietary information by patients could be used as a method of corporate espionage (e.g. Patient Jon Doe works at Vendor A, and sees Dr. Clinician, whose practices uses Vendor B. Jon Doe could obtain proprietary details on Vendor B's platform and use that information to reverse-engineer a solution or Vendor A).

In these cases, to ensure the continuity of the clinician-patient relationship, the patient profiles developed by third party data intermediaries should be accessible and exportable by the clinician for the patient, but not directly by the patient. This also promotes data privacy; fewer individuals will have access to PHI, and those with access have been prospectively verified by the healthcare organization. This is especially critical for clinicians with high-volume and high-churn practices (2a, 2b).

Quality Reporting Burden, and Transition to Digital Quality Measures

Within this RFI, we see frequent references to improving the quality reporting process while reducing provider burden. We wholeheartedly agree, and support the transition to Digital Quality Measures (dQMs), and a push to FHIR APIs that support bulk data transfers. However, we oppose turning quality reporting over to EHRs exclusively, as we have found that EHR-direct reporting can add to clinician burden, rather than reducing it. Quality reporting is tangential to the EHR's stated purpose, and we have seen that yearly changes to measures, whether additions, deletions, updates, and availability in alternate programs are often overlooked or slow to be integrated into the EHR software.

Over the last two decades, at every level of innovation, we find irregularities in EHR quality reporting results. For example, in early stages of Quality Reporting Document Architecture (QRDA) files, EHR vendors would claim the ability to generate files, but upon review, the files

included “placeholders” for the required data elements, but the actual pathway was still under construction. The result was additional provider burden, as chart pulls and supplementary documentation were required to fulfill reporting requirements.

Today, we frequently encounter false-negatives when troubleshooting discrepancies with clients. The documentation for performance is present, but Quality Reporting Document Architecture (QRDA) files indicate that performance has not been met, as the data element is not in a specific field. It is unfair to providers who demonstrate quality care, but who are not recognized because of inconsistent EHR entry instructions.

Widespread adoption of APIs and FHIR would facilitate the inclusion of alternative data sources (e.g. wearables), and would promote more meaningful and real-time quality measurement. This would alleviate issues related to data points that are often impossible to obtain in an EHR. This is particularly true in quality measures in which a data element besides age, gender, diagnosis and procedure code is required for denominator inclusion. Examples include left ventricular ejection fraction (LVEF) for cardiology-driven measures and low/medium/high risk classifications for overuse measures. A standardized method for documenting variables like these would enable clinicians to report on these measures, which are often extremely relevant, but impossible to utilize (E.4.TD-15a).

FHIR API adoption would also facilitate the reporting of additional and meaningful measures, collected from a variety of sources, without placing undue burdens on clinicians. In the context of points E.3.TD-9.e and E4.TD-15, the capability to transfer bulk data between EHRs, third party intermediaries and other vendors could substantially reduce provider burden and increase accuracy in quality reporting programs.

Thank you for the opportunity to comment on this RFI. We very much support CMS efforts to enhance patient information and to upgrade the status of patient health care data that underlies this RFI. Being a data vendor in the trenches has given us a realistic approach of not only the great enhancements that can be made in the interests of better patient care, but an understanding of the problems in EHR data, provider repositories, and clinical processes. We would be happy to elaborate on any issues herein.

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