Testimony to the Quality Measures Workgroup and the Certification and Adoption Workgroup of the Health IT Policy Committee (HITPC) for the public hearing: Ensuring the Quality of Quality Data on November 30, 2012

From
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The Medicare Quality Improvement Organization (QIO) of the Carolinas

I. Introduction

CCME is a physician-sponsored not-for-profit healthcare quality improvement organization continuously serving as the Medicare Quality Improvement Organization (or QIO) in North Carolina and South Carolina for more than 25 years. In addition, we provide services to the Medicaid program in states throughout the southeast. We are subcontractors with the ONC Regional Extension Centers in both North and South Carolina. As a result, we have much experience in assisting outpatient providers achieve meaningful use criteria. CCME also performs quality improvement projects and related research in collaboration with major academic centers.

The QIO program conducts patient safety and quality improvement activities throughout all medical settings including hospitals, outpatient medical practices, skilled nursing facilities, and home health agencies. We use data from patient medical records (paper and electronic), medical record abstractions, and administrative claims to develop quality indicators and process measures used to monitor and evaluate our activities. We have found that data quality varies greatly across medical settings and between providers within settings.

Our experience working with outpatient clinical quality measures began about 15 years ago when we introduced concepts of quality improvement and quality indicators to outpatient providers. At that time few outpatient medical practices in the Carolinas used electronic health records. Quality measures were derived from paper record abstractions of sampled patients. CCME then conducted the QIO-sponsored Doctors Office Quality - Information Technology (DOQ-IT) project in the Carolinas to assist outpatient practices in selecting and implementing EHR systems. Currently through the Regional Extension Centers and under its QIO contracts, CCME has moved from EHR implementation to the use of EHR data for monitoring and evaluating quality of care and compliance with meaningful use.

Our extensive experience working with EHR data in a variety of outpatient practices, large and small, urban and rural, throughout the Carolinas has taught us much about concerns and threats to the quality of data used to measure quality of care. Unfortunately, we can provide little hard evidence to support our comments because the accuracy and quality of these data are seldom assessed in the outpatient setting. Up until now the focus has been on the implementation of electronic systems and the development of meaningful measures using raw data from these systems. We fully appreciate the challenges that lay ahead for the health care industry and for your workgroups in the development of methodologies to improve and evaluate the quality of the data used for quality improvement, public reporting, and pay-for-performance.

We have found that physicians have deep concerns about the accuracy of quality measures. These concerns represent real threats to physician support of programs that will evaluate their patient care and impact their reimbursement for this care.

II. Threats to the quality of "raw" clinical data in outpatient electronic systems

There are many sources of potential biases and inaccuracies when using EHR-generated data to measure clinical quality. Clinical quality measures are typically derived from "raw" data collected and stored in EHR databases. These raw data may be incomplete, inaccurate, and misinterpreted. In our experience, factors contributing to poor quality raw clinical data include but are not limited to:

1. Incompletely populated databases during migration to electronic systems.
2. Fragmentation of data across multiple providers and multiple systems.
3. Inconsistent data collection methods.
4. Default values representing missing or "un-entered" data elements.
5. Inconsistent use of reminders and alerts.
6. Data collection priorities driven by reimbursement structures.
7. Variations in data collection methods/protocols (e.g., different methods of measuring blood pressure, different methodologies in performing laboratory assays, different methods of reporting pathology/radiology results, etc.).
8. Lack of a "gold standard" and common methodologies to evaluate the quality of data.

III. Threats to the quality of clinical quality measures in outpatient electronic systems

Clinical quality measures, often reported as numerator / denominator rates or proportions for specific patient populations, are only as accurate as the raw data used to calculate them. The quality of these quality measures is also influenced by the methods used to calculate them. As payers continue to review the feasibility of electronic health records to accurately report clinical measures for purposes of implementing pay-for-performance programs, several important issues must be considered. In our experience these include:

1. Variations in interpretation and calculation of measures:

The ability of EHR systems to interpret clinical quality measures and their associated exclusion criteria may vary between systems. Detailed specifications for numerators and denominators as well as exclusion/inclusion criteria need be documented and interpreted as unambiguously as possible. The accuracy of interpretation and the generation of measures from raw EHR data need to be ensured and validated in a standardized manner – such as through the provision of formal specification sheets for vendors use in coding particular measures. Independent assessments of whether these coding specifications were implemented correctly would help assure the quality of these measures.

In order to become a certified EHR product, vendors must demonstrate the ability to calculate each of the core and alternate clinical measures and three (out of 38) of the menu selections. To our knowledge, EHR vendors are not currently required to demonstrate their accuracy in calculating clinical measures or if the exclusion criteria have been appropriately programmed into the reporting capabilities of the system. Currently, the EHR vendor must demonstrate only its *ability to calculate* measures—not *accuracy in calculating* measures. If providers will be required to use their EHR generated reports to determine payment levels in a pay-for-performance environment, EHR vendors should be required to report on all 38 of the clinical quality measure menu options to give providers the greatest degree of reporting options.

Through our work assisting specialists reporting for meaningful use, we have seen that some EHR systems do not include any clinical measures that are relevant to specialties. The Stage 1 meaningful use criteria do not penalize providers since there are no benchmarks associated with measures at this stage. Providers can report a null value for numerators and denominators, this will be insufficient when benchmarks are in place and pay-for-performance is the norm.

If we are to migrate to a pay-for-performance system and base reimbursement or incentives on EHR generated clinical quality measures, the industry needs to assure the accuracy of clinical quality reports (not just the ability to generate reports) and provide standardized definitions and guidance for report calculation. Without this assurance and standardization in place, we will have wide variation in clinical measures from vendor to vendor and from practice to practice, leading providers to critically doubt the validity of the payment structure. Lack of standardization across EHR systems could lead to situations where vendor A has included different exclusion criteria in reports than vendor B. This may place providers using vendor A's software at an unfair advantage or disadvantage compared to those using software from another vendor.

There have already been instances where EHR reports have been incorrect and the vendor has publically acknowledged the error and made corrections. In some cases, providers had already attested to CMS using the incorrect reports from their certified EHR. Since the clinical quality measures at Stage 1 meaningful use do not have benchmarks, the affects of the reporting inaccuracies might be considered insignificant to CMS. If these reporting inaccuracies were to happen in a pay-for-performance environment, the affects could be financially significant leaving payers and providers in a difficult position.

2. Variations in definitions of active patient populations:

EHR databases may contain medical records for patients seen prior to their implementation. Patients may have been seen seldom if at all in clinically relevant time frames since the EHR was implemented. Our experience has shown that without a standard patient definition for denominators, clinical measures may be meaningless. A definition of "active patient" determines which patients in the EHR database are included in the measure calculation. The definition may include time. For example, active patients may be defined as patients who have been seen by the provider in the past 24 months and are not deceased. Today, EHR vendors do not have a standard definition of active patient as it is not required for EHR certification. Thus, the clinical measures reported could be misleading. Lack of a standard definition for active patients will cause reporting variations across EHR systems and could potentially place one vendor's customers at an unfair advantage or disadvantage compared to another EHR system.

3. Variations in providers' ability to document clinical data in a fully reportable manner

Our experience has shown that outpatient physician practices vary in their ability to document clinical data in a fully reportable manner. EHR generated clinical quality reports are reliant upon the provider documenting data in discrete fields as opposed to free text. In addition, providers need to document information in the exact report defined field in order for the information to be considered by the report program. Providers are dependent upon the EHR vendors reporting

documentation to know where to document key clinical information. For example, through our work helping providers achieve meaningful use we have learned that there are many discrete fields within the EHR where a provider *could* document smoking status—social history, the preventive health module, or in a clinical template—however there is only one place within the EHR that the report program will reference in calculating the measure. If we are to move into a pay-for-performance environment, we will see increasing demands for EHR generated quality report accuracy and complexity. Along with this trend, we will also see demands for an increase in the amount of provider clinical documentation. For example, when exclusions become a standard part of calculating a measure, providers will need to document any condition that could be an exclusion reason to ensure their clinical quality reports are portraying the most accurate information.

IV. Attributes of high quality data that suit outpatient physician practices.

In our experience working with EHR-generated measures in the outpatient environment, providers want measures that are accurate and truly represent the health and care of their patient populations. Providers also want quality measures to be comparable across medical practices and these measures should account for the many ways that patient populations could differ across providers. For example, providers caring for patients at higher risk for poor health and increased barriers to care (e.g., low income and uninsured patients) may feel that these factors should be taken into account when comparing their performance and those of other providers. This could be accomplished through risk adjustment and by inclusion/exclusion criteria that focus clinical measures on comparable patient subpopulations. High quality clinical data would be required to generate fair and comparable measures in a consistent and reliable manner. Characteristics of these data would include:

1. Quality measures should be based on standard definitions of patient populations (standard denominators) using consistent inclusion/exclusion criteria across all EHR vendors and implementations.

2. High comparability and standard reporting of lab, pathology, radiology, and procedure results across providers.

3. Quality measures should be associated with clear and feasible vendor-supported implementation protocols which specify how raw data are to be measured and collected by EHR systems.

4. Vendor-specific quality measures should be independently certified as accurately calculated prior to official release.

5. Quality measures should calculated in such a way that they are comparable across providers when variations in patient populations and other factors may be expected to influence measures.

6. Numerator and denominator timeframes should align for each patient and measure.

V. Issues related to common barriers to meaningful exchange and quality reporting in the health IT enabled environment and structured data.

Our work in the area of care coordination has revealed that technical and administrative barriers to meaningful exchange of quality reporting data has a major impact on patient care, confidence in clinical care measures, and the efficiency of the medical system. There are two aspects of this problem with especially high impact: 1) Timely sharing of standardized post-discharge information from hospitals to outpatient and home-health providers, 2) Medication lists for reconciliation across health care settings. These are major causes of health care failures leading to avoidable re-admissions for recently discharged patients such as those with heart failure, myocardial infarction, and pneumonia. Health care data are frequently not available across medical settings and when they are, its relevance, accuracy, and meaning are frequently in question resulting in redundant collection and recording of data and in potential for patient safety issues.

VI. What are lessons learned from activity in Stage 1 Meaningful Use that can be applied to the future for the common barriers listed above? What experience have HIEs gained in managing data quality in MU setting? Is there a need for and opportunities for alignment of data quality standards for MU, PQRS, IQR, commercial and beyond? What level of testing and auditing is required or should be for ensure quality?

Our experience with helping hundreds of outpatient medical practices achieve Stage 1 Meaningful Use standards and our work with practices in reporting of PQRS data have suggested –

1. At the level of outpatient practices, there is much potential for variation in

    a. Methods to collect raw data used for quality measures.

    b. Methods to store raw data in EHR databases (e.g., which fields contain which clinical information).

    c. Methods to use raw data in the calculation of clinical quality measures.

    d. Methods to identify denominator populations for quality measures.

2. There is a need to ensure that outpatient practices collect and use raw data in a standard well-defined manner.

3. There is a need to ensure that EHR vendors provide consistent and independently certified measures in their software products that are comparable across vendors. We understand that certification software and systems are being developed to address this need in Meaningful Use Stage 2. This need should be fully addressed across all relevant measures prior to the use of EHR data for pay-for-performance.

4. Alignment of quality measures across all programs has the potential to ensure greater confidence, accuracy, and comparability of measures. Alignment of value sets, codes, and logic will further accomplish this goal.

5. Quality testing or auditing is needed but should not be performed in a manner that would further burden providers without compensation. Assessment of data accuracy could be performed using independent auditors – but providers will be challenged to reproducibly provide data to auditors – this could be a big cost.

VII. Is there a policy need that the HITPC can address? Is there only a technical need that the HITSC can address?

There will be much work for many potential stakeholders, vendors, and contractors if the fullest realization of high quality data is to be achieved. Specific policy changes, if needed, should align with and support the needs of outpatient providers as described above.

If physicians will be required to submit quality data (pay-for-reporting/performance) then they will need assistance and structure to meet reporting deadlines, technical quality assurance support to make sure data is reported/received on time, and help handling the other myriad of issues associated with submitting data.

1. We recommend a continued prominent role for Medicare's national system of Quality Improvement Organizations (QIOs) to ensure high quality EHR data is available in the future. QIOs have long supported important data validation and collection functions across medical settings and through Regional Extension Centers. For example, QIO experience in supporting hospital quality data reporting has been found to be an essential service. QIOs are perfectly positioned to support these services to physicians in outpatient settings.
2. We recommend an alignment of quality measures across provider settings so that improvement efforts could be coordinated and approached at a community level – this will ease data interpretation issues as communities gear up to resolve care coordination problems.
3. We understand that ONC will be developing eCQM certification for Meaningful Use Stage 2, but certification of "non-meaningful use" eCQM would not be required. We recommend that a similar more universal process be federally required for all eCQM.
4. We recommend including outpatient providers and their patients in policy development related to issues of data quality.