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Thank you for the opportunity to provide testimony today. We commend this panel, the Office of the National Coordinator (ONC) and the Centers for Medicare and Medicaid Services (CMS) for their continued efforts to seek comments on how the industry, ONC and CMS can collaborate to improve the support of electronic clinical quality measurement.

I am Andrew Mellin, MD, MBA, Vice President and Medical Director of Enterprise Intelligence, McKesson Provider Technologies, a division of McKesson Corporation. My team is responsible for the development, implementation and support of data analytics and quality measurement solutions for our hospital and physician customers. I am testifying today on behalf of McKesson Corporation, a Fortune 14 company with decades of experience leading the health information technology (health IT) industry. McKesson supports the largest and most diverse provider customer base in the health IT industry, including 50 percent of all health systems with 77 percent of those with more than 200 beds, 20 percent of all physician practices and 25 percent of home care agencies, representing more than 50,000 home care visits annually. We also process billions of financial healthcare transactions between physicians, hospitals, insurers and financial institutions, and provide care and claims management solutions to most of America’s health insurance companies. RelayHealth, McKesson's clinical connectivity business, is a participant in community and regional health information exchanges and connects patients online with their physicians, hospitals and health plans.
McKesson’s perspective on the importance of the quality of quality data is based on our years of experience developing health IT software and service solutions that empower healthcare professionals with the information they need to deliver better care to their patients. Our solutions include electronic health records (EHRs), automation and robotics, financial and administrative systems, and connectivity and interoperability software applications. Our McKesson Enterprise Intelligence™ suite of products support analytics for the enterprise healthcare organization by aggregating the right clinical, financial and operational data from all settings, including acute care, physician practice, home and others and transforming it into actionable information. Enterprise Intelligence uses predefined healthcare metrics, healthcare benchmarks and both real-time and retrospective performance analytics to help health care organizations make strategic decisions to transform data into useful information that influences the action of every stakeholder in the healthcare system to improve the quality, safety and efficiency of care.

**Current Attributes, Metrics and Standards for Ensuring Data Quality**

The quality of data within an EHR can largely be measured by its accuracy, integrity, consistency, timeliness and completeness. When considering these attributes in the context of data capture within the EHR, McKesson employs several approaches to ensure data quality:

1. Preventing data entry errors through several strategies including:
   - Implementation of data entry validation rules to ensure, for example, that dates are entered in the correct format, numeric entry fields have out-of-range checking whenever possible and key data fields are marked as “required” to ensure the completeness of the data;
   - Utilization of standards when appropriate for clinical documentation to ensure that data appears in a consistent content nomenclature and uses a standard terminology. These standards include the use of prescribed value sets to represent similar clinical or administrative concepts. Each value set is a list of specific values (terms and their codes) derived from single or multiple standard clinical terminologies or administrative code sets.
These standards ensure consistency of the data across the EHR and support clinical quality measurement and health information exchange;

- Importation of data directly from monitoring devices or other systems to prevent errors with manual re-entry; and
- Utilization of clinical decision support to ensure data integrity and accuracy validation; for example, alerting the clinician to incongruence between the sex of the patient and a diagnosis or procedure entered.

2. Employing a team of highly specialized content and terminology experts to manage the deployment of evidence-based clinical content and rules that utilize standard terminologies and mapping of the data. This team is also responsible for the detailed analysis of the electronic clinical quality measure (eCQM) specifications and value sets to ensure the accurate capture of all necessary data elements within our products.

3. Enabling point of care documentation functionality so that the EHR supports the entry of data at the point of care within the clinician’s workflow. This helps ensure the data entry process is timely, accurate, and complete and that the process takes advantage of the value of real-time clinical decision support and ultimately drives better patient care. In addition, McKesson supports a model that promotes the single entry and ongoing validation of cross setting of care clinical data, such as the problem list, allergies, and medication

4. Implementing policies and procedures for EHR database managers to assure that EHR data in clinical databases are accurate by:

- Ensuring that whenever possible, data is only entered one time and then utilized throughout the system. For example, when prescribing medications, the system uses key data previously entered during the patient assessment such as, height, weight, sex and diagnoses, to provide individualized patient alerts or reminders;
• Assuring user authentication to restrict access and documentation to authorized clinical personnel, and database management to authorized technical personnel;

• Employing referential integrity checking processes and tools, including the use of validation tables that contain the “rules” and “data scrubbing” capabilities, to ensure correctness, meaningfulness, and security of the data. For example, a rule may check to ensure that certain data comes from a valid code set or is in a specified format

• Preventing intrusion of “hostile traffic” by implementing network intrusion detection capabilities;

• Using state of the art back-up systems to assure complete data in the event of a system disruption or corruption;

• Performing data and hardware integrity validation to prevent data loss due to corruption or disk failures; and

• Utilizing industry standard technology to ensure consistency during data transmission from the source system to the receiving system.

Do stakeholders and end-users have different expectations for data quality?

Stakeholders and end-users of clinical data represent a broad cross-section of personnel across the healthcare spectrum. For the purposes of this testimony, they are grouped as measure stewards, healthcare organizations, physicians and other caregivers, patients and payers.

For physicians, caregivers, and healthcare systems, the electronic medical record serves first and foremost as a mechanism to capture and communicate the information on the current patient condition, thought processes and reasons for decisions, actions taken and plans for the future. Providers have a long history of interest in the quality of medical record data to both prevent clinical errors (e.g., through accurate lab data)
and document their sound medical practices. These stakeholders additionally have strong interest in the accuracy of clinical quality measurement reports to assure an accurate reflection of their standard of care.

Payers have a keen interest in the accuracy of reported data to ensure appropriate reimbursement and to obtain insight into their analysis of key risk areas and performance and quality strategies. Both payers and providers share strong incentives for accurate clinical data. Providers want to ensure that their documentation of the patient’s record captures the documentation to support a level of reimbursement commensurate to the effort and complexity of the patient’s care, according to the Evaluation and Management (E&M) and Current Procedural Terminology (CPT) coding standards. Payers want to assure the documentation accurately represents the quality of care and the actual care provided. However, the data required for accurate coding for billing purposes is only a small subset of the data actually need for patient care.

Patients expect their medical record to be 100% accurate and presented in terms that are familiar to him or her. Given the many stakeholders that “touch” a patient record and the lack of specificity of some coding standards, the patient is often surprised to see incorrect documentation that may occur when a provider chooses a coded term that is close but not exactly like the patient problem, or when a billing coder chooses an incorrect billing code that is never validated clinically and has no impact on payment. Patients and their caregivers also become frustrated when errors impact care or payer coverage and reimbursement decisions.

Measure stewards, which are organizations responsible for the development, endorsement and use of clinical quality measures, have particular interest in the accuracy of data used for quality reporting. These organizations, which range from clinical specialty professional associations to large accreditation bodies, construct quality measures based on clinical science in the development process. Often this leads to specifications that require collection of data elements which may not be collected during the typical
caregiver workflow or are not directly relevant to communicating patient care in order to satisfy measure logic requirements that are insignificant to the overall measure outcome. For example, a quality measure may specify detailed exclusion criteria to explain the reasons why the actions recommended by the quality rule were not provided. This could include clinician documentation of specific religious reasons, patient preference choices, or prior diagnoses and procedures that have no direct relevance to the care being provided to the patient during this encounter. This leads caregivers to document simply in order to satisfy the measure which may not be an accurate or necessary representation of patient care. Given the expected increase in the number of measures, the link to reimbursement, and the exponential degree of difficulty in collecting many of these data elements in an accurate and complete manner, the requirement for realistic feasibility testing should be a requirement of the selection process for federal quality measurement programs.

Federal agencies such as the CMS should consider attributes of data quality that track both clinical and technical data quality for attestation programs such as the EHR Incentive Program. The CMS should also consider the implications of the documentation requirements for providers and weigh the burden of the collection of voluminous amounts of data against the efficiency and accuracy of the desired outcome. For example:

- eCQM specifications should be tested for feasibility of data within the EHR and only require the minimum data necessary which must be collected beyond that readily available in an EHR.
- Exclusion and exception data requirements have been demonstrated by Stage 1 to be extremely difficult to collect and should be avoided whenever possible. Documenting all of the many reasons care is NOT delivered requires considerable workflow interruption, user interface development, and clinician training for successful data capture, and has not been proven to materially change the overall accuracy of population outcomes.
• There must be existing and established clinical processes, standards and workflow to accommodate the collection of the data. For example, Meaningful Use Stage 1 introduced the objective of maintenance of a patient problem list. While this is an easy technical software development requirement, physicians and other caregivers struggled with the implementation. Maintaining a high quality clinical problem list that is complete and accurate in coverage of all active, resolved and inactive chronic and acute conditions is an ongoing workflow and implementation challenge, especially in the acute care environment. Additionally, the move towards a cross-setting, multidisciplinary problem list has added even greater complexity, resulting in numerous operational questions. Who was ultimately responsible for the patient problem list? How should ordinality of diagnoses (Principal, Secondary and so forth) be captured, along with the clinical attributes such as active and resolved? How are other specific attributes required by the eCQM specifications captured? Today, the dependence on manual review and data entry for problems that cross care and provider settings does not support the data collection requirements and business processes for care delivery. It will take a focused and concerted initiative to develop standard practice for all aspects of the clinical and business processes to achieve this goal.

• Prior to the adoption of new Meaningful Use objectives and any associated quality measurement requirements, CMS should consider the maturity of the clinical processes and the standards available to support both the objective and the quality measures. For example, many of the new Stage 2 objectives for the EHR incentive program lack clinical definitions, defined workflow processes, and mature standards, such as a “Longitudinal Plan of Care”. In addition, some standards may need to be enhanced or developed in their entirety. Before introducing new meaningful use objectives and clinical quality measures, CMS and ONC should review and validate implementation that supports clinical practice, ensure that established standards
exist, and defer criteria which do not have clinically accepted standards and definitions until these can be fully developed.

Data quality becomes especially important, although sometimes problematic, when it is shared with other providers with potentially disparate systems. Once messages pass between systems, the quality of data may deteriorate through data mapping and translation. For example, one of the critically important areas of patient information that must be shared is the problem list, which may be documented using either SNOMED CT or ICD9 codes. In order to share this data, mapping between the two code sets must exist. In many instances, there is not a specific one-to-one mapping available, which leads to loss of fidelity of the problem list accuracy. Standards that support this type of issue must be established, in order to ensure that the data is both semantically as well as technically correct. These quality issues will become more pronounced as transmission cycles develop, such as transmission of allergy data from system A to system B to system C, and then back to system A again. As the sharing of data becomes widespread between multiple providers and EHRs, it will become critical to address this data quality accuracy issue with some quantitative method of evaluating the quality and accuracy of the data.

What role do providers and patients play in ensuring currency and accuracy of EHR data quality?
Hospitals, clinicians and patients have a keen interest and play a pivotal role in assuring the currency and accuracy of EHR data quality. Strong governance and content standards exist for provider episode-of-care medical records and are enforced. Although patient-centric health information is shared across multiple health care settings and providers, standards are lacking for longitudinal health records. Professional associations with an interest in medical record integrity recognize the need for governance and content standards for longitudinal health records and are beginning to develop the policies and standards to support these efforts. Technology is quickly evolving to meet the goal of longitudinal medical records; however,
adoption will only be assured when development of longitudinal health records requires strong content, records management and ownership governance standards.

When considering the quality of data within an EHR, we have found that clinicians may assume that data is accurate by virtue of being electronic, not requiring validation. For example, a patient entering the Emergency Department is seen by the triage nurse with access to the patient’s record through the sharing of data from the primary care physician. The nurse reviews the patient’s active medication list, but may not validate the information with the patient or caregiver, as he/she assumes the data is accurate even though the patient could have seen other providers which are not reflected in the EHR. Just as is the case with paper medical records, validation of electronic data is a critical step and must be performed to the extent possible in order to ensure data integrity and accuracy. Patients and their caregivers can often evaluate the accuracy of their information better than anyone else. Additionally, patients continue to want greater access to their medical information and should increasingly play an active role in reviewing their data and providing validation and any necessary corrections.

The addition of data from outside sources in formats such as a Continuity of Care Document (CCD) makes the validation process even more critical with multiple external contributors and exponentially greater quantities of information. It is imperative to provide functionality that ensures the review and documentation of critical values by key clinical providers.

As EHR development evolves, it will be important to develop solutions to automate quality measurement in a more efficient and effective way. Quality measures were originally developed using manual extraction by trained analysts during chart reviews. Early EHR systems developed organically with more focus on documentation efficiency than on data capture for quality measurement and decision support. Next generation EHRs must incorporate quality reporting as an essential process of care. McKesson applauds
about recent developments which will support a transition from these legacy data issues to more sophisticated offerings:

- Measure developers, the National Quality Forum (NQF), CMS and the ONC are looking for ways to partner with vendors and providers to better understand workflow and electronic data. Along with our customers, McKesson is collaborating with the quality measure experts in order to understand how to create measures that work within clinician workflow that includes EHRs. As a result, all stakeholders are beginning to evaluate the process to measure the real-world feasibility of electronic data collection for quality measurement.

- McKesson is focused on assisting our customers to implement their systems to facilitate data capture and clinician workflow in a standardized manner to support both quality measurement and clinical decision support. Once in place, we can add decision support tools such as real-time quality dashboards. Clinical quality reporting must evolve from the current state of retrospective reminders of missed care opportunities to real-time information at the point of care.

Clinicians find the process of combing through extensive data burdensome in order to understand the true picture of the patient. Clinicians also stress that the most important feature of the patient’s EHR is to clearly present the story of the patient, highlighting key information in order to make the right clinical decision. Today, there is a convergence of efforts underway with measure developers and measure stewards, technology tools and provider organizations to drive towards automated and enhanced quality measurement. A clear and concise patient record view provides an opportunity for all stakeholders to agree on the essential clinical data needed to both drive quality measurement and the clinical care process, while ensuring the quality of the data used for the patient’s EHR.

Conclusion
In closing, we commend ONC and CMS for the tremendous investment made to advance clinical quality measurement through EHRs. The reliability and validity of any electronic clinical quality measure (eCQM) is dependent upon the quality of the data used to compute that measure. We recommend that ONC and CMS consider the following suggestions to optimize the quality of data used to support clinical quality measurement efforts in the EHR Incentive program:

- Before introducing new quality measures, CMS and the measure developers should review and validate implementation that supports defined clinical processes. Required data elements can be more efficiently and accurately gathered within the provider’s workflow, if these elements are already collected as a byproduct of the care process and stored in the EHR. In addition, ONC and CMS should continue to support the development of related standards, especially in areas where key standards gaps exist.

- Electronic Clinical Quality Measures should be developed de novo for use in EHRs, and should undergo feasibility testing during the development process. Projects such as the National Quality Forum (NQF) eMeasure Feasibility Testing Project, currently in progress, are critically important to this effort, and McKesson supports and applauds this effort.

- CMS and ONC should continue to support collaboration opportunities to include hospitals and physicians, measure developers, EHR vendors, and federal agency program staff in the measure development, selection, validation and implementation process.

- CMS, ONC and the National Library of Medicine (NLM) should enhance efforts to align the clinical value sets across all measures to avoid measure-specific “similar but not the same” value sets and ensure the standardization of clinical concepts for both data capture and reporting purposes.

- Measure Developers should ensure that the eCQM specifications focus on data elements that have a high level of value for all stakeholders so that the measures are more likely to be captured.
consistently. During the measure development process, we encourage collaboration among measure developers, providers and vendors to help validate this process.

On behalf of McKesson, thank you for the opportunity to share our insights and recommendations. We welcome further dialogue on these issues and look forward to working with you as you consider the recommendations presented today.

I would be pleased to answer any questions.