**STATEMENT OF**

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**BEFORE THE**

**OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY**

**STANDARDS COMMITTEE’S IMPLEMENTATION WORKGROUP**

**REGARDING CONSOLIDATED CLINICAL DATA ARCHITECTURE IN STAGE 2 MEANINGFUL USE**

**July 28, 2014**

Good morning Co-chairs and distinguished members of the HIT Standards Committee Implementation Workgroup. Thank you for inviting me to testify on the state of Consolidated Clinical Data Architecture (C-CDA) in Stage 2 Meaningful Use. My name is Charles Curran, and I currently serve in product management for RelayHealth, McKesson’s connectivity business. I am here today on behalf of more than 15,000 McKesson employees who work every day on the development and deployment of health information technology (IT) solutions that improve the quality, safety and efficiency of patient care.

I lead product management for RelayHealth Clinical Solutions Data Platform and Acquisition Tools group, which builds, manages and supports our C-CDA processing, among other product capabilities. RelayHealth Clinical Solutions provides cloud-based scalable HIE, patient engagement and platform services solutions to our customers and partners, which include:

* Hundreds of health systems and hospitals including all customers using McKesson’s Horizon and Paragon electronic health record (EHR), and a large number of health systems seeking an enterprise patient portal which meets the “View, Download and Transmit” functionality;
* The US Department of Defense as part of the Defense Health Agency’s global patient-centered medical home initiative;
* Tens of millions of patients with secure messaging and health record access and
* Member organizations of the CommonWell™ Health Alliance, for which we serve as the pilot service provider.

RelayHealth is in a unique position to evaluate the current state of Consolidated CDA as part of Stage 2 Meaningful Use. In our work, both for our health system customers, our hospital EHR partners, and the Department of Defense, we transact both Continuity of Care Documents (CCD) and Consolidated CDA documents at a current rate of more than 5.5 million documents per month and growing, with the vast majority of those documents currently conforming to C-CDA from Edition 2014 certified EHRs. We not only move those documents from place to place as part of our health information exchange (HIE) and Direct HISP functionality, but we also parse and aggregate the discrete clinical information to a consolidated record, which we display both to providers as part of an HIE and to patients as a View, Download and Transmit Edition 2014 certified enterprise patient portal. We currently process C-CDA documents for a number of acute and ambulatory EHR systems, including McKesson Paragon and Horizon, Cerner, Epic, Siemens, Meditech, Allscripts, GE, eClinicalWorks, NextGen, athenahealth and many others. In addition, in our work as the pilot service provider for CommonWell, we have observed C-CDA handling by CommonWell members in production, including McKesson, Cerner, Allscripts, athenahealth and Greenway.

Based on our extensive experience, McKesson believes that the industry is making progress in interoperability. However, we note limitations of the existing implementations of the C-CDA at this point in time which impede the level of interoperability expected by industry stakeholders.

In our work, we have noted some current issues with C-CDA as a document and data standard, which I will summarize here.

* As a document standard:
  + C-CDA currently has multiple limitations. The typical experience of a clinician is to view a vendor-specific style sheet that may be many tens of pages, without a way to receive a pertinent summary of the clinical status of the patient or to view only subsets of the data such as the active medication list, without paging through multiple screens of information.
* As a data standard:
  + C-CDA is poorly constrained in parts that vendor and sometimes EHR-specific configurations must be developed to parse critical sections, including medications, problem lists and allergies and medication intolerances.
  + There is such variation in how “no known” medication intolerances and “no known” environmental/substance allergies are handled that special casing of SNOMED terminology by the vendor is required.
  + C-CDA does not handle data versioning; therefore, data correction in the case of errors requires manual intervention.
  + Many C-CDA instances have more specificity in the narrative section of each section than in the discrete data section. Because of this, some vendors have even proposed that we parse the XML narrative text rather than handle missing information in the discrete data sections.

Accordingly, the Office of the National Coordinator for Health IT’s (ONC) proposed performance standard of handling 95% of the received C-CDAs would require intermediaries such as RelayHealth to accommodate all of the vendor-specific variations. At this stage, most EHR vendors have simply defaulted to “View-only” solutions rather than parsing and handing discrete clinical data.

I have included more detailed information on these limitations in the written testimony we provided to you.

In our judgment, C-CDA is better and more tightly constrained than the CCD standard which it replaced. However, the overall experience of supporting C-CDA has been more problematic than the experience of supporting CCD because the timeframe for support was far more rapid. We implemented more than 325 hospitals between April and July of this year in an accelerated timeframe, with the vast majority of these organizations “going live” in the 45 days immediately preceding the July 1st, 2014 fiscal year start date for Stage 2. Although McKesson EHRs were certified within three months after the publication of the Final Rule, this accelerated deployment was necessitated by the accelerated timelines to certify, test and finalize for general release, roll out to hospitals, locally test, train and certify for production and finally bring technology live to meet a fixed “drop dead” date.

We recommend that the HIT Standards Committee and the ONC address these issues in the following ways:

1. Publish more detailed and constrained specifications and implementation guidance including clinical use cases to address common issues causing variance, such as the handling of current and non-active medications, problems, allergies and the comingling of the terms medication intolerances and environmental/substance allergies..
2. Publish conformance tools to accompany the implementation guides to optimize and validate real world instances of C-CDA and a standardized style sheet rendering of C-CDA
3. Evaluate standards and implementation guidance that separates clinically relevant narrative content from the accessible discrete information. We recommend using FHIR to bundle a narrative summary with accompanying discrete resources; alternatively, future C-CDA documents could deliver a brief clinical narrative separately from the packaging of discrete clinical data without the need to render each section’s narrative text or machine abstract the document.
4. Recommend that significantly more time than was allowed for Stage 2 Meaningful Use be provided for future phases of meaningful use and other certification-related and timeline driven regulatory programs. This additional time will allow for the appropriate use, testing, deployment and other activities such as the improvement of implementation guidance and incremental refinements for both standards and implementations.

We appreciate the opportunity to share our perspective with the HIT Standards Committee Implementation Workgroup on the state of Consolidated Clinical Data Architecture (C-CDA) in Stage 2 Meaningful Use today. We have a shared goal of enabling interoperability and we thank you for the work you do to improve interoperability in practice.

Thank you.

# Detailed Background Information

## Documentation Limitations

In practice, providers receive views that span tens of pages of screens worth of information, including both current and historical information that must be read to discover the essential clinical information that triggered the clinical event on transition. As a result, many clinicians are expressing frustration about the poor user experience and some express a preference for paper and faxed documents.

Most C-CDAs combine a vendor-specific style sheet (XSLT) transformation with a complete set of clinical information, often containing the patient’s entire medical history. Because of attestation and safety requirements, EHR vendors do not want to constrain what information is provided and tight workflow considerations make it difficult to impossible for providers to select subsets of information provided in a C-CDA document. Likewise, the default “transformation for view” does not provide or make clinical decisions about what information to include on the first page of the rendered view. In summary, there is a conflict between the desire by EHR vendors to provide complete information and the desire by clinicians to receive summarized and clinically relevant textual views. Since most EHRs do not automate reconciliation, but default to the transformed views, the current state provides no usability of clinically relevant textual summaries and none of the benefits of clinically accurate discrete data.

In addition, documents received from different vendors are less readable in the target system than in the originating system. This occurs because of the unique vendor interpretation of the C-CDA format, including what information the vendor choses to display or not in the textual portion of each section, and the associated style sheet. To improve usability, we have created a feature that allows style sheets to be uploaded and applied to each vendor’s C-CDA. Our concern is that this workaround does not meet the goal of true interoperability.

## Data Limitations

There are multiple areas where C-CDA is underspecified or where C-CDAs in the real world do not adequately conform to existing specifications. Here are examples of where C-CDA is underspecified, necessitating vendor and sometimes instance-specific interpretation of rules:

* Null and Null handling in C-CDA is highly complex with practically every element and attribute potentially “nullable” resulting in poor clinical interpretations that implementations may need to address.
* In some cases, the textual sections of the C-CDA are fully populated, although the structured sections are missing the same data found in the textual sections. This prevents the incorporation of data into a longitudinal record.
* We have found multiple instances where active status on medications, problems and allergies/intolerances are not provided. In some cases, a “missing status” is to be interpreted as an active medication and in in other cases the same missing status is to be interpreted as an “inactive medication”
* The allergy section combines allergies and intolerances to medications, allergies to food and environmental allergies. Therefore, to express the concepts such as “no known medication allergies/intolerances” in a fully interoperable way is problematic. A common pattern is to express such statements with negations of certain SNOMED-CT (SCT) codes, although there is no consistent guide as to which SCT codes are to be used. These results in the development of vendor-specific rules rather than the universal use of a common standard.

The following are real world examples where C-CDA documents do not conform to specifications:

* Frequently received C-CDA documents are invalid. In some of these cases, C-CDA documents are generated using an integration engine or are produced using a 2014 edition certified EHR that in practice has been customized locally. In other cases, we have found invalid XML as part of a conformant document.
* There are multiple instances where codes and declared value sets do not match. For example, a medication may be expressed as an RxNorm value, although the associated code is not a valid RxNorm code.
* We have observed numerous examples where textual information and coded discrete data do not match. This mismatch leads to a situation where the view provided by the style sheet is in conflict with the view we derive from the parsed coded data.
* The handling of negation indicators is inconsistent across vendor instances, even in areas where the standard is clear.

Although we have had our technology certified by the ONC accredited testing bodies multiple times and worked closely with hospitals and practices seeking to achieve Stage 2 meaningful use with Edition 2014 certified EHR technology, our customers’ have not advanced to productive use in preparation for the 90-day attestation period. We had multiple teams of engineers working full time to address in-production mismatches between business logic that was certified and accredited and real world C-CDA documents. We continue to find issues in production with each new type of EHR we support.

As noted in our testimony, we recommend that ONC immediately work with standards development organizations, such as HL7, to better specify C-CDA implementation guidance with clinically valid examples and normative translations of those clinical examples to valid C-CDA. Such clinical examples should be clinically informed use-cases, include both positive and negatives cases, address the clinical interpretation of missing data and the requirements for information necessary for clinical interpretation (e.g., active status). These examples should also specifically address how to handle missing and “no known” medication intolerances, and other substance and environmental allergies on a normative basis.

Additionally, we recommend the development of conformance testing tools that can be operationalized to validate aberrant types of C-CDA documents from Certified Electronic Health Record Technology (CEHRT) and recommended style sheets to deliver a consistent rendering of conformant C-CDA instances.