

Glide Path from HITSP C83 to C-CDA: Informed decision making for health information stakeholders

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1. Introduction

1.1. Audience

The audience for this white paper are health information technology (HIT) executives, program leaders, system architects, and healthcare professionals who are engaged in implementing electronic exchanges of patient clinical information between provider organizations. More specifically, this white paper is aimed at Beacon Programs or other community-based exchanges who have invested significant effort in the 2010 – 2012 timeframe on interoperability solutions for community-based exchanges employing Health Level 7 (HL7) and Health Information Technology Standards Panel (HITSP) specifications known as C32 and C83.

1.2. Purpose

The purpose of this document is to provide an intuitive summary of the history and current state of standards and specifications for clinical document exchange in healthcare. This paper also addresses the implications that new Stage 2 Meaningful Use (MU) standards will have on prior work efforts, and in particular, the work of Beacon Communities. Finally, this paper offers guidance to HIT decision makers and implementers on a pathway to use of the new standards promoted by Centers for Medicare and Medicaid (CMS) and the Office of the National Coordinator for Health Information Technology (ONC).

1.3. Background

The HITECH Act and Interoperability Standards for Meaningful Use

Included in the American Recovery and Reinvestment Act (ARRA) of 2009 was the \$22 billion Health Information Technology for Economic and Clinical Health Act, or HITECH Act. Among its many provisions was establishment of an Electronic Health Record (EHR) Incentive Program to be managed by CMS and a complementary EHR Certification Program to be managed by ONC. Both are aimed at rapidly increasing EHR adoption and meaningful use by American hospitals (eligible Hospitals) and eligible professionals (EP). Additionally, these programs promote standards-based electronic exchange of patient information between health providers to improve the quality and reduce the cost of healthcare.

Both the EHR Incentive Program and the EHR Certification Program stipulated use of then-existing HIT standards for clinical information exchange. For summary records of patient care these included the HL7 Continuity of Care Document (CCD) as described in the Health IT Standards Panel (HITSP) interoperability specification C32 and a competing standard developed by the American Society of Testing and Materials (ASTM) called the Continuity of Care Record, or CCR. In Stage 1 of the MU rules (2011-2013), providers and hospitals were only required to demonstrate a test CCD/C32 or CCR exchange with another provider. While the HITSP C32 has been the more highly adopted standard in this period, it has not been entirely successful at enabling true interoperability between healthcare systems and EHRs. There are good examples of C32 implementation and use, particularly as a means of creating human readable patient summaries. But the creation of a conformant C32 by one entity and the ability to effectively consume that document by another system as structured data proved very challenging – resulting in few system to system interoperability examples. There was an obvious need for an easier to use, less ambiguous, more constrained implementation guide for CCD than existed in the HITSP C32 specification.

Beacon Community Program

The HITECH Act also established the Beacon Communities Program. This \$250 million Cooperative Agreement with the Department of Health and Human Services (HHS) Office of National Coordinator selected 17 communities to demonstrate how health IT investments and meaningful use of EHRs can transform healthcare toward a more patient-centered model, while achieving the three-part aim of better care, lower cost and better population health. Communities were selected that had already made progress in EHR adoption, health information exchange, and clinical quality improvement. Each of the 17 communities prepared its own plan, focused on its unique strengths and population health needs, and endeavored to:

- Build and strengthen the health IT infrastructure and exchange capabilities within communities, positioning each community to pursue a new level of sustainable healthcare quality and efficiency over the coming years;
- Translate investments in health IT to measureable improvements in cost, quality and population health, and
- Develop innovative approaches to performance measurement, technology and care delivery to accelerate evidence generation for new approaches.

Beacon Communities leveraged the momentum generated by meaningful use with plans to create measureable community value by employing EHR systems to perform electronic exchange of clinical information. CCDs were viewed as a vital contributor to:

1. Improve care coordination on the occasion of a patient referral from primary care to specialist and back to primary care.
2. Provide detailed clinical encounter data to centralized Beacon data systems such as a clinical repositories or disease registries.

The data requirements of these Beacon Communities and their use cases often exceeded the data content specified in a C32. Additionally, ambiguity in the implementation guidance for the C32 led to poor interoperability results when these electronic documents were exchanged between different EHR products. As a result the Beacon Communities, with very limited timeframes to perform their grant objectives, organized with EHR vendors to form a Beacon-EHR Vendor Affinity Group to tackle interoperability issues that were placing Beacon objectives at risk.

Beacon – EHR Vendor Affinity Group

With the support of the ONC, the Beacon – EHR Affinity Group (AG) was formed in December of 2011 to collaborate on several Beacon needs. Over the next year, this collaboration led to a consensus specification for a CCD document called the C83. This more precise definition was established using HITSP C83 content modules that were in highest demand by the Beacons and could reasonably be supported by the majority of participating EHR vendors. This joint definition process enabled the provisioning of content not required of the C32 and developed strong commitment on the part of the EHR vendors to provide data in a highly structured and encoded fashion that was required to meet the semantic interoperability requirements of the Beacon Programs.

Beacon use cases and a CCD content specification based on C83 content modules were published in May 2012. In August 2012, each Beacon Community identified physician practices where the resulting CCD specification would be piloted. A total of 32 medical practices across 12 Beacon Communities and six EHR vendors were identified as pilots. Most pilots were scheduled for

completion in November 2012, and demonstrated the effectiveness of CCD-based clinical exchange in supporting care transitions and feeding community clinical repositories or disease registries.

Introduction of the Consolidated CDA for Stage 2 Meaningful Use

In August 2012, CMS and ONC published the final rules for Stage 2 MU and the 2014 Edition of the EHR Certification Requirements. In doing so, an important step was taken to encourage greater use of standards-based, electronic exchange of patient information to improve care coordination and patient engagement. Specified in the Stage 2 rules is the use of the Consolidated Clinical Document Architecture (C-CDA) specification as the prescribed means for electronic exchange of patient care summaries. A balloted draft *Implementation Guide for CDA Release 2.0, Consolidated CDA Templates (U.S. Realm)*, was released by HL7 in December 2011. According to HL7 the Consolidated CDA provides a single-source library of reusable templates for construction of C-CDA documents, including the Continuity of Care Document. The C-CDA updates and supercedes templates and implementation guidance created by HITSP, including the C32 and C83.

The ONC's Standards and Interoperability (S&I) Framework team created a *Companion Guide to HL7 Consolidated CDA for Meaningful Use Stage 2*, available in draft form at the time of this publication. This Companion Guide supplements the C-CDA specification and provides additional practical guidance from the Transition of Care Initiative to implementers striving to meet Stage 2 MU requirements.

1.4. Objectives

For Beacon Communities and other organizations who have invested in HITSP specific implementations of the CCD (C32 or C83) there are reasonable concerns about the Stage 2 MU and 2014 Edition EHR Certification rules and implications they may have on future work. For example, Beacon leaders may wonder about the wisdom of extending their C83 implementations versus waiting for vendors to support the CCD specification found in the C-CDA.

The objectives of this White Paper are to:

1. Provide a concise history and status of clinical content standards, the organizations that create them, and their intended use.
2. Summarize the clinical exchange requirements of Stage 2 MU and the content standards required in the CMS and ONC rules.
3. Present results of a comparative analysis of the Beacon Community data requirements and how these needs are met by the new Stage 2 MU clinical summary standard.
4. Provide guidance to Beacon program managers and others on the best path forward during 2013 – 2015 from HITSP-based specifications of CCD to C-CDA specification of CCD.
5. Capture a bibliography of additional resources for additional learning.

2. Current State of Content Standards

2.1. Brief History of Clinical Exchange Standards

The Evolution of a Standard

Clinical data exchange standards have been evolving continuously since the mid 1980's along with the information technologies supporting such standards. With the advancement of the internet over the past 20 years there has been a shift to healthcare standards built on internet based technologies such as HTTP/S, web services and extensible markup language (XML). Many of these standards are produced by Health Level 7 (HL7) and profiled by other organizations such as the American Society for Testing and Materials (ASTM), Integrating the Healthcare Enterprise (IHE) International, and the HITSP in order to meet needs of specific clinical use cases.

In 2001, HL7 produced the Reference Information Model (RIM) as part of the larger HL7 version 3 standard. The RIM is the basis for all HL7 v3 information models and structures, one of these being CDA. CDA Release 1 was published as Draft Standard for Trial Use (DSTU) in 2000, and was the first HL7 specification to be derived from the RIM. This was followed by CDA Release 2 published in 2005. CDA is an American National Standards Institute (ANSI)-approved HL7 standard.

In 2006, Continuity of Care Record (CCR) was published by ASTM and considered by many an alternative to CDA Release 2, and thus began a CCR vs CDA competition for adoption. In the interest of providing a solution that met the needs of both standards, HL7 joined forces with ASTM to produce the CCD, combining the content specifications from CCR with structural components in CDA. This effectively resulted in a CDA R2 document with CCR content.

In 2005, IHE created a new domain for development called Patient Care Coordination (PCC). PCC focuses on integration issues that cross providers, patient problems or time. In its first year PCC produced a profile called Exchange of Personal Health Record (XPHR) that uses CCD (in its draft form) as a base standard. Several other profiles using CCD as a base standard have been published since then, and PCC continues its work to harmonize with current and future content standards such as C-CDA.

In 2004, the Office of the National Coordinator for Health IT (ONC) was established by President Bush to advance the use of HIT in the United States. ONC subsequently created HITSP in 2005 to focus on harmonizing a multitude of emerging healthcare IT interoperability standards across the public and private healthcare sectors. In 2009, HITSP worked on profiling several interoperability standards to align with the initiatives of the ARRA. The resulting work included references to several IHE PCC profiles, which in turn include references to CCD. One of these is the *HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component*, or more commonly known as "C32". HITSP C32 leverages much of the work previously done in IHE PCC XPHR, CCD and CDA, adding national extensions for a US specific implementation.

There is a progression of standards created by various Standards Development Organizations (SDOs), each building upon and improving the work of others. By 2010, these standards evolved to the HITSP C32 which became the target implementation for Stage 1 MU and the EHR Certification Program. The chain of references is as follows: HITSP C32 references IHE PCC XPHR, which references CCD, which references CDA R2 and pulls clinical content from CCR. This progression of standards can be seen in Figure 2.1-1 below beginning with the founding of IHE in 1997 and leading up to the publication of C-CDA in 2011.

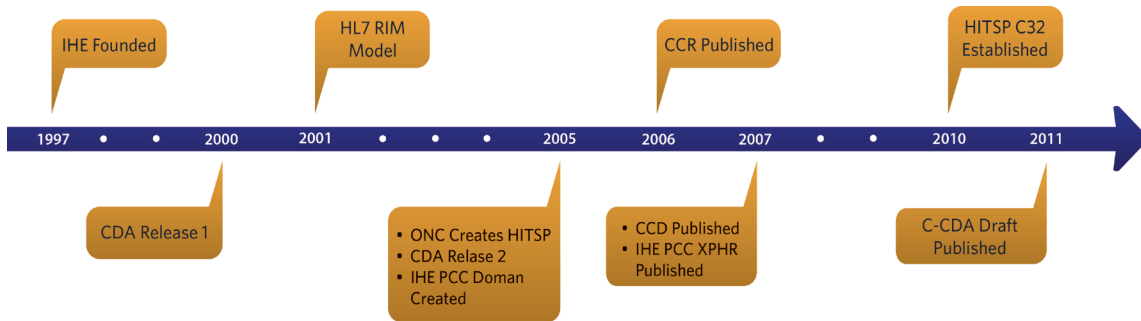


Figure 2.1-1 Standards Timeline

Key Participants in Standards Setting and Adoption

The creation of early healthcare interoperability standards usually begin with Standards Development Organizations (SDOs) followed by profiling organizations that provide implementation guidance around specific use cases. Profiling organizations are often comprised of members from both public and private entities, delivering in a balanced approach to what the public and private HIT sectors need.

In addition to the development and implementation of HIT standards, coordination and incentives are needed to drive forward adoption of such standards in the marketplace. This occurred with the introduction of the HITECH Act in 2009, which has led to the creation or expansion of various federal standards promoting groups including the Health IT Standards Committee (HITSC), the Health IT Policy Committee (HITPC), the eHealth Exchange (formerly NwHIN), and the Federal Health Architecture and the S&I Framework teams within ONC.

Participation of commercial HIT vendors is equally important as they bring experience from real-world implementations. Vendors understand what works, along with what does not work. Their feedback can deliver opportunities for improvement and reduce the risk of lethargic adoption.

Stage 1 Meaningful Use and HITSP C32

In 2010, the MU Stage 1 Final Rule was released, which included HITSP C32 as one option for representing clinical content in a certified system. The CCD leveraged the robustness of CDA and the content guidance provided in CCR. Today, CCDs are utilized internationally across systems spanning a multitude of medical disciplines. The subsequent publication of HITSP C32 as well as other HITSP constructs, has led to further adoption in the United States of the CCD as a base level standard.

Profiling is used extensively to provide implementation guidance around existing standards, allowing the focus to be on a very specific clinical use case. Profiling ultimately creates building blocks for new and more mature standards in some cases. However profiling does come with its own challenges, often in the form of complexity. In the case of the content standards being discussed here, this is like an onion with many layers, and most of the layers must be peeled back in order to achieve a successful implementation. In other words, an implementer of HITSP C32 must also understand IHE XPHR, CCD and CDA and either buy, build or adopt the appropriate tools to build these base standards.

As indicated above, it is not without a few challenges stemming from extensive optionality, relaxed requirements on use of structured data versus text, and both complexity and ambiguity in

implementation guidance. Combined with the weaknesses in C32, this led to limited success in EHR to EHR interoperability. The C32 can be made to work as a vehicle of exchange between two provider EHRs but, as a standard, it was not sufficient in and of itself to guarantee a successful, semantically useful exchange between any two applications.

2.2. Leveraging HITSP C83 to Meet Beacon Data Exchange Requirements

Concurrent with the publication of Stage 1 MU rules, the Beacon Communities Program was launched by ONC to provide real-world demonstration of the effectiveness of HIT to improve our healthcare system. Many of the 17 Beacons planned to immediately employ standards-based clinical exchanges to improve the coordination of patient care in their communities for the practices and patients participating in the Beacon project. Many of these Beacon Communities were actively engaged in establishing health information exchange (HIE) infrastructure, clinical repositories, and disease registries to collect, aggregate, and analyze clinical data to support their stated objectives. This too required the exchange of clinical data from practice EHR systems to the Beacon data systems. Beacon pioneered adoption of the HITSP C32 standard for communicating clinical information between healthcare providers. The Virtual Lifetime Electronic Record (VLER) program conducted by the Department of Veterans Affairs (VA) and Department of Defense (DoD) Health Affairs represented another large program attempting similar interoperability outcomes.

This section provides a brief synopsis of the Beacon EHR AG effort to leverage HITSP standards for Beacon objectives in a consistent way with many EHR systems. Some of the reasons for this approach include adopting a standard that supports multiple clinical scenarios; the reuse of existing standards; and the ability to extend templates if and when needed.

The data content needs of Beacon Communities vary greatly, and thus a content standard that offers flexibility is required to ensure that the highest level of adoption possible is achieved across implementations. The HITSP C32 Summary Document is a document specification that leverages section and entry templates from HITSP C83 and was included as part of the MU Stage 1 regulation. While a “Summary Document” contains useful information, it is by nature targeted at a specific set of use cases not allowing for the variation needed across Beacon/EHR interoperability implementations. Thus, AG efforts have focused around the use of C83, prioritizing content templates, and constraining value sets as needed.

Benefiting from annual interoperability testing at IHE North America Connectathons, HITSP C83 became a natural choice for Beacon programs. One of the goals of the AG was not to create new standards, but to leverage existing ones, and this choice of a standard meets that goal as well.

3. Future of Content Standards as Informed by MU Stage 2

3.1 Description of Stage 1 Meaningful Use Content Standards

Stage 1 MU is comprised of 15 core requirements and 10 menu requirements for EPs. Among these, seven require some form of electronic data exchange and four require creation of a HITSP C32 CCD or ASTM CCR document for either exchange or provision to patient on electronic media or in human readable form. These requirements and the standards ONC specified to support them are identified in Table 1 below.

In general, Stage 1 MU was intended to encourage broad EHR adoption but would only begin the journey to EHR interoperability. The requirements for exchange were relatively low bars to meet and frequently required little more than a test. The EHR vendor community was likewise immature in the use and deployment of these standards leading to first-generation C32 implementations that varied widely in quality and content. While some EHR vendors technically met the limited requirements of a human readable electronic document, they were a long way from enabling strong system-to-system semantic interoperability.

Table 1. Stage 1 Meaningful Use for Eligible Providers Summary Record Exchange Requirements and Standards

Stage 1 MU Objective EP	Stage 1 MU Measure	Stage 1 MU Certification Criteria	Stage 1 MU Standards
<p>(CORE 12) Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request</p>	<p>More than 50% of all patients of the EP who request an electronic copy of their health information are provided it within 3 business days</p>	<p>§170.304(f) - Electronic copy of health information Enable a user to create an electronic copy of a patient’s clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in:</p> <ul style="list-style-type: none"> (1) Human readable format; and (2) On electronic media or through some other electronic means in accordance with: <ul style="list-style-type: none"> (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: <ul style="list-style-type: none"> (A) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and (C) Medications. The standard specified in §170.207(d) 	<p>Patient summary record. §170.205(a)(1) - HL7 CDA Release 2, CCD. Implementation specifications: HITSP Summary Documents Using HL7 CCD Component HITSP/C32. §170.205(a)(2) - ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369. Problems. §170.207(a)(1) - The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions. §170.207(a)(2) - IHTSDO SNOMED CT July 2009 version. Laboratory test results. §170.207(c) - LOINC version 2.27, when such codes were received within an electronic transaction from a laboratory. Medication. §170.207(d) - Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.</p>

Stage 1 MU Objective EP	Stage 1 MU Measure	Stage 1 MU Certification Criteria	Stage 1 MU Standards
<p>(CORE 13) Provide clinical summaries for patients for each office visit</p>	<p>Clinical summaries provided to patients for more than 50% of all office visits within 3 business days</p>	<p>§170.304(h) - Clinical summaries Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:</p> <ul style="list-style-type: none"> (1) Provided in human readable format; and (2) Provided on electronic media or through some other electronic means in accordance with: <ul style="list-style-type: none"> (i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and (ii) For the following data elements the applicable standard must be used: <ul style="list-style-type: none"> (A) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2); (B) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and (C) Medications. The standard specified in §170.207(d). 	<p>Patient summary record. §170.205(a)(1) - HL7 CDA Release 2, CCD. Implementation specifications: HITSP Summary Documents Using HL7 CCD Component HITSP/C32. §170.205(a)(2) - ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369. Problems. §170.207(a)(1) - The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions. §170.207(a)(2) - IHTSDO SNOMED CT July 2009 version. Laboratory test results. §170.207(c) - LOINC version 2.27, when such codes were received within an electronic transaction from a laboratory. Medication. §170.207(d) - Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.</p>

Stage 1 MU Objective EP	Stage 1 MU Measure	Stage 1 MU Certification Criteria	Stage 1 MU Standards
<p>(CORE 14) Capability to exchange key clinical information (for example problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically</p>	<p>Performed at least one test of certified technology's capacity to electronically exchange key clinical information</p>	<p>§170.304(i) Exchange clinical information and patient summary record</p> <p>(1) <i>Electronically receive and display.</i> Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.</p> <p>(2) <i>Electronically transmit.</i> Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in accordance with:</p> <p>(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and</p> <p>(ii) For the following data elements the applicable standard must be used:</p> <p>(A) <i>Problems.</i> The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);</p> <p>(B) <i>Laboratory test results.</i> At a minimum, the version of the standard specified in §170.207(c); and</p> <p>(C) <i>Medications.</i> The standard specified in §170.207(d).</p>	<p>Patient summary record.</p> <p>§170.205(a)(1) - HL7 CDA Release 2, CCD.</p> <p>Implementation specifications: HITSP Summary Documents Using HL7 CCD Component HITSP/C32.</p> <p>§170.205(a)(2) - ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369.</p> <p>Problems.</p> <p>§170.207(a)(1) - The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions.</p> <p>§170.207(a)(2) - IHTSDO SNOMED CT July 2009 version.</p> <p>Laboratory test results.</p> <p>§170.207(c) - LOINC version 2.27, when such codes were received within an electronic transaction from a laboratory.</p> <p>Medication.</p> <p>§170.207(d) - Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.</p>

Stage 1 MU Objective EP	Stage 1 MU Measure	Stage 1 MU Certification Criteria	Stage 1 MU Standards
<p>(MENU 8) The EP who transitions their patient to another setting of care or provider of care or refers their patient to another setting of care should provide summary of care record for each transition of care or referral</p>	<p>The EP who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals</p>	<p>EP §170.304(i) - Exchange clinical information and patient summary record</p> <p>(1) Electronically receive and display. Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, medication allergy list in accordance with the standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.</p> <p>(2) Electronically transmit. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list in accordance with:</p> <p>(i) The standard (and applicable implementation specifications) specified in §170.205(a)(1) or §170.205(a)(2); and</p> <p>(ii) For the following data elements the applicable standard must be used:</p> <p>(A) Problems. The standard specified in §170.207(a)(1) or, at a minimum, the version of the standard specified in §170.207(a)(2);</p> <p>(B) Laboratory test results. At a minimum, the version of the standard specified in §170.207(c); and</p> <p>(C) Medications. The standard specified in §170.207(d).</p>	<p>Patient summary record.</p> <p>§170.205(a)(1) - HL7 CDA Release 2, CCD. Implementation specifications: HITSP Summary Documents Using HL7 CCD Component HITSP/C32.</p> <p>§170.205(a)(2) - ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369.</p> <p>Problems.</p> <p>§170.207(a)(1) - The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions.</p> <p>§170.207(a)(2) - IHTSDO SNOMED CT July 2009 version.</p> <p>Laboratory test results.</p> <p>§170.207(c) - LOINC version 2.27, when such codes were received within an electronic transaction from a laboratory.</p> <p>Medication.</p> <p>§170.207(d) - Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.</p>

3.2 New Content Standards for Stage 2 Meaningful Use

While Stage 1 MU was all about EHR adoption and properly capturing patient clinical data in an EHR, Stage 2 MU goals provide portability to the data allowing it to be shared with other providers on relatively disparate systems. Stage 2 MU requires successfully sending and receiving (consuming) clinical summaries from other EHR systems. Here the goal is to improve care coordination by making the contents of the patient record portable and comprehensible to another EHR and another provider. In the end, both the sender and receiver must have the same understanding of the data.

The data must therefore be highly structured. It must be encoded with standard medical terminologies uniformly used by all EHRs. The electronic document conveying these clinical data must conform to a specification created with true semantic interoperability in mind. It must be easy to implement correctly and hard to implement incorrectly. To meet these goals a further refinement of standards for a summary record was needed. The C32 specification was not adequate to the task. The platform for achieving these goals is the C-CDA standard. The C-CDA, created by a project carried out by the ONC's S&I Framework as the CDA Consolidation Project, was developed through joint efforts of HL7, IHE, the Health Story Project and ONC.

These standards bodies solicited feedback from a wide range of Stage 1 MU content implementers and found that much of the problem was concentrated in following three issues associated with C32 development:

1. Multiple Sources of the "Truth".
2. Overly complicated standards referencing (i.e. circuitous pointers to other documents).
3. Very little potential for Code/Object Reuse.

Implementing C32 content involved referencing the below implementation guides/sets that inform HITSP's C32:

- HL7's CDA R2;
- CCD;
- IHE's PCC XPHR Profile ;
- HITSP's C32;
- C83 – data templates; and
- C80 – vocabularies/coding systems.

Consequently, each individual rule lookup could potentially have numerous reference points found across many technical volumes. It is the primary goal of C-CDA to organize all rules into a single, easily used implementation guide. A recent Gartner blog notes that due to the significant difficulties in interpreting C32, that, "the process of deciding which was right was a bit like Talmudic disputation, with the rabbis being the analysts of each firm and the sacred documents being the four or five different documents that had to be used simultaneously in order to find interpret the C32." The possibility for multiple interpretations combined with the inherent ambiguity involved with 'multiple sources of truth' result in increased potential for error. Additionally, these conditions could deliver differing component-level (e.g., problems, medications, vitals, etc.) interpretations across

the various CDA document types, which, in turn introduced software development problems and laborious problem solving.

To help counter these problems, the C-CDA authors combined the rule-sets associated with the above three guides, and drafted a new 'Template' hierarchy beginning with Document-level templates, followed by Section, then Entry level templates. Primary goals for the templates include:

- Streamlined development by providing reusable building blocks;
- Quicker implementation: users can implement once, and deploy often;
- Since they are modular, templates (such as blood pressure, discharge diagnosis) can be repackaged with other templates in any number of other CDA implementation guides; and
- Provisions for "incremental interoperability," in that one can begin with simple CDA, and then add templates as they are prioritized.

The Section and Entry templates should look relatively familiar since the rule-sets are largely unchanged from HITSP. However, the C-CDA implementation guide defines nine different types of commonly used CDA documents and related document templates; each having different section requirements appropriate to the care setting and episode that it supports.

1. Continuity of Care Document
2. Consultation Notes
3. Discharge Summary
4. Imaging Integration, and DICOM Diagnostic Imaging Reports
5. History and Physical
6. Operative Note
7. Progress Note
8. Procedure Note
9. Unstructured Documents (not permissible under Stage 2 MU)

These templates were derived in accordance with ONC's Certification Criteria for Certified Electronic Health Record Technology (CEHRT), 2014 Edition, and are directly related to the three EP objectives that require the use of the C-CDA standard.

Table 2 summarizes these three objectives, and measures, certification criteria and standards associated with each.

Table 2. Stage 2 Meaningful Use for Eligible Providers Summary Record Exchange Requirements and Standards

Stage 2 MU Objective EP	Stage 2 MU Measure	Stage 2 MU Certification Criteria	Stage 2 MU Standards
<p>(CORE) Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.</p>	<p>1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.</p> <p>2. More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.</p>	<p>§ 170.314(e)(1) (View, download, and transmit to 3rd party)</p> <p>(i) EHR technology must provide patients (and their authorized representatives) with an online means to view, download, and transmit to a 3rd party the data specified below. Access to these capabilities must be through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).</p> <p>(2) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data:</p> <p>(1) The Common MU Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).</p> <p>(2) Ambulatory setting only. Provider's name and office contact information.</p> <p>(3) Download.</p> <p>(1) Electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in human readable format or formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):</p> <p>(i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1) and (2) of this section.</p> <p>(C) Transmit to third party. (1) Electronically transmit the ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) of this section in accordance with the standard specified in § 170.202(a).</p> <p>(ii) Activity history log.</p> <p>(A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:</p> <p>(1) The action(s) (i.e., view, download, transmission) that occurred;</p> <p>(2) The date and time each action occurred in accordance with the standard specified at § 170.210(g); and</p> <p>(3) The user who took the action.</p> <p>(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.</p> <p><i>*Depending on the type of certification issued to the EHR technology, it will also have been certified to the certification criterion adopted at 45 CFR 170.314 (g)(1), (g)(2), or both, in order to assist in the calculation of this meaningful use measure</i></p>	<p>§ 170.210(f) Encryption and hashing of electronic health information. Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140-2 (incorporated by reference in § 170.299).</p> <p>§ 170.204(a) Accessibility. Standard. Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).</p> <p>§ 170.205(a)(3) Standard. HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the "unstructured document" document-level template is prohibited.</p> <p>§ 170.202(a) Standard. ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).</p> <p>§ 170.210(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).</p>

Stage 2 MU Objective EP	Stage 2 MU Measure	Stage 2 MU Certification Criteria	Stage 2 MU Standards
(CORE) Provide clinical summaries for patients for each office visit.	Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.	<p>§ 170.314(e)(2) (Ambulatory setting only— clinical summary)</p> <p>i) Create - Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at §170.205(a)(3).</p> <p>ii) Customization - Enable a user to customize the data included in the clinical summary.</p> <p>iii) Minimum data from which to select - EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary: Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set). The provider’s name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids.</p> <p><i>*Depending on the type of certification issued to the EHR technology, it will also have been certified to the certification criterion adopted at 45 CFR 170.314 (g)(1), (g)(2), or both, in order to assist in the calculation of this meaningful use measure.</i></p>	<p>§170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the “unstructured document” document level template is prohibited.</p>

Stage 2 MU Objective EP	Stage 2 MU Measure	Stage 2 MU Certification Criteria	Stage 2 MU Standards
<p>(CORE) The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.</p>	<ol style="list-style-type: none"> 1. The EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals. 2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either-- <ol style="list-style-type: none"> (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. 3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: <ol style="list-style-type: none"> (A) Conducts one or more successful electronic exchanges of a summary of care document, as part of which is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or (B) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period. 	<p>170.314(b)</p> <ol style="list-style-type: none"> (1) (Transitions of care—receive, display, and incorporate transition of care/referral summaries). <p>§ 170.314(b)</p> <ol style="list-style-type: none"> (2) (Transitions of care—create and transmit transition of care/referral summaries). (b) Care coordination. <ol style="list-style-type: none"> (1) Transitions of care – receive, display, and incorporate transition of care/referral summaries. <ol style="list-style-type: none"> (i) Receive. EHR technology must be able to electronically receive transition of care/referral summaries in accordance with: <ol style="list-style-type: none"> (A) The standard specified in § 170.202(a). (B) Optional. The standards specified in § 170.202(a) and (b). (C) Optional. The standards specified in § 170.202(b) and (c). (ii) Display. EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(1), § 170.205(a)(2), and § 170.205(a)(3). (iii) Incorporate. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to: <ol style="list-style-type: none"> (A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient. (B) Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s): <ol style="list-style-type: none"> (1) Medications. At a minimum, the version of the standard specified in § 170.207(d)(2); (2) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3); (3) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(2). (C) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)(3). (b)(4) Clinical information reconciliation. Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type: <ol style="list-style-type: none"> (i) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date. (ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems. (iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user's confirmation, automatically update the list. 	<p>Receive, Display and Incorporate</p> <p>§ 170.202 Transport standards. The Secretary adopts the following transport standards:</p> <ol style="list-style-type: none"> (a) Standard. ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299). (b) Standard. ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299). (c) Standard. ONC Transport and Security Specification (incorporated by reference in § 170.299). <p>§ 170.205 (a) Patient summary record –</p> <ol style="list-style-type: none"> (1) Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299). (2) Standard. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in §170.299). (3) Standard. HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the "unstructured document" document-level template is prohibited. <p>§ 170.207(a)(3)Standard. IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).</p> <p>§ 170.207(d) (2) Standard. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in § 170.299).</p>

Customization, Incorporation and Section View

Three new EHR behaviors are described and specified as requirements in the 2014 certification criteria for CEHRT. These behaviors give the provider greater control over the content and use of exchanged C-CDA clinical documents, both when sending a clinical summary and when receiving one from another provider. EHR technology across various care settings must be able to generate outgoing C-CDA documents such as CCD based on provider instructions at time of referral or discharge as well as incorporate incoming care summaries.

For incoming C-CDAs there is an incorporate requirement specified in the ONC Certification Criteria – 170.314(b)(1). This will enable a user to discretely incorporate data in the medications, medication allergies, and problems sections of a C-CDA into their patient’s EHR. That is the minimum threshold and other sections can be included. If those sections aren’t available for incorporation they need to be made available at a section level.

Section view is outlined as well in the 2014 EHR certification criteria. Each section of a C-CDA is required for individual display along with the header of the document. This capability was added in order to allow the user to see the desired sections without having to navigate through a long C-CDA.

While the data requirements vary a bit between summary types, they all start with what has been defined as the “Common MU Data Set” (see below). Creating case-specific documents would then involve adding other applicable sections (e.g., Immunizations, Family History, Functional Status, etc.).

Common MU Dataset Section Components

Patient Name	Race	Medications	Care Team (members)
Sex	Ethnicity	Allergies	Care Plan
Date of Birth	Preferred Language	Vital Signs	Lab Tests
Smoking Status	Problems	Procedures	Lab Test Results

3.3 How the Beacon C83 requirements compare to the MU Stage 2 C-CDA requirements

As discussed earlier, Stage 1 MU had minimal content requirements in the required HITSP C32 CCD. This led to poor content and ultimately left a gap in shared data. The Beacon Community took on as a task to voluntarily increase the data requirements of the underlying specification, the HITSP C83 document.

For MU Stage 1 all that was required was:

- Problems;
- Active Medications;
- Active Medication Allergies; and
- Diagnostic Test Results.

An example of the loose requirements for the C32 CCD is the requirements in the medication section. Ultimately, the only hard requirement was the Free Text Product Name (8.15). There were some “Required if Knowns” including Coded Product Name, Coded Brand Name, Type of Medication and Status of Medication. This set a low bar to be met for a valid document.

With this in mind the Beacon Community set out to constrain the document and come to an agreement on further requirements. The first step being to identify what data was valued and then which data points were priority. While virtually all of the data was identified as valued, 66 individual data elements were identified as priority and the rest for future consideration.

Table 3 below summarize the Beacon data requirements from the C83 specification and compares these to the data requirements in the updated CCD document within the C-CDA standard. The HITSP C83 document sections map closely to the C-CDA sections. You will see on the left side highlighted in green the sections containing those 66 elements required by the Beacon C83 project. On the right side highlighted in blue, the Stage 2 MU Common Data Set requirements. Additionally, in red you will see further data requirements as outlined in specific measures.

You will see that the Beacon C83 requirements map very closely with the Stage 2 MU Common Data Set requirements. The significant elements of the Stage 2 MU Common Data Set for C-CDA that is not found in the C83 and thus, not in the Beacon exchange requirement, is Plan of Care and associated scheduled laboratory testing. In general, Beacon needs appear to be well met by C-CDA requirements in the Stage 2 MU Common Data Set and exceeded when additional C-CDA modules are added, such as encounter medications or reason for referral.

Table 3. Beacon C83 requirements compared to Stage 2 MU C-CDA Requirements

Section Content Modules (HITSP C83)	Beacon C83 Required Sections in Green	C-CDA Template	Stage 2 MU Data Elements <i>Blue indicates Common MU Data Set</i>
C83 Header	C83 Sect ID	C-CDA General Header Template	
Personal Information	1	recordTarget/patientRole	
		patient/name	Patient Name
		patient/administrativeGenderCode	Patient Sex
		patient/birthTime	Patient Date of Birth
		patient/raceCode	Patient Race
Language Spoken	2	patient/ethnicGroupCode	Patient Ethnicity
Information Source	10	patient/languageCommunication	Patient Preferred Language
Healthcare Provider	4	author	
		informant	
		Component Of	
		encompassingEncounter/responsibleParty	Provider Name and Office Contact Information
		encompassingEncounter/encounterParticipants	Care Team Members
		encompassingEncounter/effectiveTime	Admission and Discharge Dates; Date of Visit
encompassingEncounter/location	Admission and Discharge Location; Visit Location		
		documentationOf/serviceEvent	
		assignedEntity/assignedName	Care Team Members

Section Content Modules (HITSP C83)	Beacon C83 Required Sections in Green	C-CDA Template	Stage 2 MU Data Elements <i>Blue indicates Common MU Data Set</i>
C83 Body Sections		C-CDA Section Template C-CDA Entry Template	
Allergies and Other Adverse Reactions	6	Allergies (entries required)	Medication Allergies
Medications (incl. Current Meds)	8	Medications	Medications
		Medications Administered	Medications Administered during the Visit
Admissions Medication History		Hospital Admission Medications	
Hospital Discharge Medications		Hospital Discharge Medications	Medications (Inpatient)
		Hospital Discharge Instructions	Discharge Instructions (Inpatient)
Problem List	7	Problem (entries required)	Problems
			Encounter Diagnoses (ambulatory?)
Active Problems			
History of Past Illness		History of Past Illness	
Hospital Admission Diagnosis		Hospital Admission Diagnosis	Encounter Diagnoses (inpatient?)
			Reason(s) for Hospitalization (Inpatient)
ED Diagnoses			
		Postprocedure Diagnosis	
Postoperative Diagnosis		Postoperative Diagnosis	Encounter Diagnoses (Inpatient)
Discharge Diagnosis		Hospital Discharge Diagnosis	

Section Content Modules (HITSP C83)	Beacon C83 Required Sections in Green	C-CDA Template	Stage 2 MU Data Elements <i>Blue indicates Common MU Data Set</i>
C83 Body Sections		C-CDA Section Template C-CDA Entry Template	
Chief Complaint		Chief Complaint	Reason(s) for Hospitalization; Reason for Visit
		Chief Complaint and Reason for Visit	
Reason for Referral		Reason for Referral	Reason for Referral
History of Present Illness		History of Present Illness	
List of Surgeries	17	Procedures (entries required)	Procedures
Procedures and Interventions			
		Instructions	Clinical Instructions; Recommended Patient Decision Aids
Functional Status	N/A	Functional Status	
		Functional Status Result Observation	Functional Status
		Functional Status Problem Observation	
		Cognitive Status Result Observation	Cognitive Status
		Cognitive Status Problem Observation	
Discharge Diet		Discharge Diet	
Advance Directives	12	Advance Directives	
Immunizations	13	Immunizations (entries required)	Immunizations; Immunizations Administered during the Visit
Physical Exam		Physical Exam	
Vital Signs	14	Vital Signs	Vital signs (height, weight, BP, BMI)

Section Content Modules (HITSP C83)	Beacon C83 Required Sections in Green	C-CDA Template	Stage 2 MU Data Elements <i>Blue indicates Common MU Data Set</i>
C83 Body Sections		C-CDA Section Template C-CDA Entry Template	
Review of Systems		Review of Systems	
Hospital Course		Hospital Course	
Diagnostic Results	15	Results	Laboratory Value(s)/Result(s)
Assessments		Assessments	
Assessment and Plan		Assessment and Plan	Care plan field(s), including goals and instructions
Plan of Care (may include Procedure Orders)		Plan of Care	Laboratory Test(s)
		Plan of Care Activity Observation	Diagnostic Test(s) Pending; Future Scheduled Test(s)
		Plan of Care Activity Encounter	Future Scheduled Appointments; Referrals to Other Providers
		Plan of Care Activity Act	
Family History	18	Family History	
Social History	19	Social History	Smoking Status
		Smoking Status Observation	
Pregnancy	9	Pregnancy Observation	
Encounters	16	Encounters	
Medical Equipment		Medical Equipment	
Payers	5	Payers	
Comment			
Purpose			

4. Transition Scenarios from C83 to C-CDA (generically and for Beacons)

4.1. Gaps from C83 to Meaningful Use Stage 2

While the Beacon C83 does align well with many of the Stage 2 MU data requirements, there are several Stage 2 MU data requirements that are not encompassed by the 66 Beacon priority C83 data elements. Of the 36 unique data requirements identified across the five 2014 Edition EHR Certification objectives that require the use of C-CDA, 15 are not currently included in the Beacon priority data elements, as noted in the table below.

2014 Edition Certification Data Requirements not met with C83 priority elements	
Care plan field(s), including goals and instructions	Location of Admission and Discharge
Clinical Instructions	Location of Visit
Cognitive Status	Reason for Hospitalization
Diagnostic Tests Pending	Reason for Referral
Discharge Instructions	Reason for Visit
Functional Status	Recommended Patient Decision Aids
Future Appointments	Referrals to other Providers
Future Scheduled Tests	

These data requirements may be captured within the Beacon C83 in non-priority elements, or in an unstructured format across several elements, but in order to meet 2014 Edition Certification objectives, they must be captured in a structured manner within the appropriate containers defined by the C-CDA standard. Additionally, in some cases, medical vocabularies may need to be migrated from what is in use today, as many of the 2014 Edition Certification objective data requirements have explicit corresponding vocabulary requirements such as Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT) for problems.

While not necessarily surprising, the C83 as implemented by Beacons does not meet all data requirements of Stage 2 MU and the C-CDA. Beacons, however, have a shorter path to Stage 2 MU minimum requirements by virtue of their work with C83 than those who never fully implemented a HITSP summary record exchange in Stage 1 MU.

4.2. Possible Transition Paths

The C83, while not the standard required by the ONC 2014 Edition EHR Certification Criteria, is a logical precursor to the C-CDA standard, and as such has both similar structures and contains much of the data required. In order to meet the 2014 Edition EHR Certification Criteria, effort will need to be applied in three areas.

1. The first gap to be closed is capturing and being able to output the data required across the various certification objectives.
2. The second gap is ensuring that the vocabularies identified in the ONC Certification Criteria are used when including the required data elements.
3. The third gap is adjusting the format of the structured document to comply with the C-CDA document templates.

While it is likely incrementally less effort to stay with the C83 construct and chip away at the data and vocabulary requirements, cutover to the C-CDA format will likely be a significant change, and as such may make sense to tackle in parallel. For operational purposes, organizations tackling this transition will need to plan for mixed-mode operation for some duration, supporting both current and Stage 2 MU compliant formats.

4.3. Implications for Transport

From a transport perspective, the 2014 Edition Certification Criteria is strongly anchored in the Direct protocols, including optional support for the XDM/XDR transforms of the standard. Like many other content standards, Direct was designed intentionally to be content-agnostic, and as such, the transition from C83 to C-CDA should have no impact to the transport layer, other than coordination between senders and recipients.

4.4. Enabling Tools to Support the Transition to C-CDA

While the C-CDA standard was intended to simplify implementation of CDA, it still remains a daunting 600+ page standard that requires fluency with CDA R2 principles to be successful. Luckily, several community resources are available that can help accelerate transition efforts.

- C-CDA and IHE North America Connectathon testing
(<http://www.iheusa.org/IHEUSA-Connectathon-Registration-ConsolidatedCDA.aspx>)

As organizations progress through their implementation efforts of C-CDA, there are community events where practical cross-organizational information exchange testing occurs which can help harden an implementation. One such upcoming event is the IHE NA Connectathon being held in Chicago, Ill. from January 28 – February 2, 2013. This will be the first time when an IHE Connectathon specifically plans interoperability testing of C-CDA documents.

- Model Driven Health Tools (MDHT)
(<https://www.projects.openhealthtools.org/sf/projects/mdht>)

The Model Driven Health Tools (MDHT) effort was started with the intention of encapsulating complicated content models into programming APIs and developer tools, so that by simply using the APIs, implementers can ensure compliance with the underlying model. The libraries are written for use with Java environments, and are already being used in production environments by several stakeholders.

The MDHT project has a full model based upon C-CDA which has been updated to reflect the July 2012 updates to the standard. The libraries can be used to both construct properly-formed C-CDA documents as well as validate C-CDA documents received from external sources.

- The S&I Framework's Companion Guide to Consolidated CDA for Meaningful Use
(<http://wiki.siframework.org/Companion+Guide+to+Consolidated+CDA+for+Stage+2+MU>)

The Transitions of Care Initiative within ONC's S&I Framework has been developing a detailed analysis of the 2014 Edition Certification Criteria requirements for C-CDA and are publishing it as a Companion Guide for the C-CDA standard. The Companion Guide includes an explicit mapping of the clinical data requirements from the certification criteria to unique templates within the C-CDA standard, and spells out a recommended approach for building structured documents that will both adhere to the standard and meet the 2014 Edition Certification Criteria. Additionally, it provides references to educational and resources that might be helpful in bringing a team up to speed on the C-CDA standard or accelerating implementation efforts.

4.5. Best Approaches for Transition (2013-2014)

As the Beacon Grant draws to a close in 2013, establishing ongoing support for and a glide path to evolving standards via the C-CDA becomes even more crucial to the long-term success of integration efforts. Transition of work accomplished within the Beacon Communities in the handling and integration of electronic documents, in particular CCDs, informs a need for greater consistency in standards which will facilitate improved interoperability. It is imperative for those Communities and Exchanges charged with moving these initiatives forward to consider increased or continued involvement as the standard evolves.

Monitoring of authoritative sources of information such as HL7, IHE, and the S&I Framework CDA Harmonization Workgroup, participation in informational meetings, webinars, conference calls and testing opportunities (e.g., IHE North America Connectathon), the development of white papers, and partnering with HIE and EHR vendors will be just a few ways in which the work of the Beacon Communities Program and EHR AG will continue.

Monitoring of authoritative sources should not be limited to the occasional review of web sites and published documents, but an informed familiarity accomplished through engagement and evaluation as the standard continues to evolve. Where integration efforts have and will rely on agreed upon standards, the more substantive the evaluation of how each document, section and entry evolves, integrates, and interoperates, the more substantive the value and impactful feedback to those who facilitate the development of the standard will be.

With the intent of the C-CDA being to clarify the standard for the sake of making it easier to understand, implement and analyze, active participation in those organizations that are facilitating the development of the C-CDA standard is essential. As a valuable source of opinions and experiences, those who use these standards among multiple vendor platforms need to contribute to the harmonization of existing standards. The success of the Beacon Communities and the EHR AG leveraged regular participation in conference calls with vendors (and SDOs) which allowed for the sharing of these experiences. This type of interaction, along with the development of white papers for example, presents Communities and Exchanges the opportunity to share informed feedback and learn from the expertise, experience, and perspectives of others.

5. Risk Analysis

The movement from HITSP C83 and C32 documents to C-CDA has many long term benefits to a well-connected healthcare community. It does however pose certain challenges or risks to organizations and communities already invested in C83 or C32 implementations. Among these are:

1. Risks associated with multiple standards and specifications being employed simultaneously through the transition period. This will be a concern for EHR vendors, HIEs, Beacons and other community or regional users of summary clinical records. An uneven adoption rate of Stage 2 MU standards and the C-CDA can be expected and may pose some operational complications even beyond 2014.
2. Risks associated with vocabulary selection changes as specified in the Stage 2 MU rule. SNOMED CT for example, is the required code system for Problem lists and not International Classification of Diseases (ICD)-9. Additionally, by the end of 2014 many providers will have transitioned to ICD-10 for diagnosis coding. These changes can impact downstream data systems like registries and repositories and can reduce quality and cost comparability across years in which data is encoded differently.

3. Risks associated with provider use of EHR systems to properly capture structured and encoded data. EHR systems will need to be the source of well-formed, coded clinical observations and results. Where standard codes for diagnosis and procedures have been commonly embraced by EHR and Patient Management systems for billing purposes, new code systems for tests (LOINC), medications (RxNORM), and problems (SNOMED CT) are essential to the integrity and accuracy of expressing clinical meaning in electronic documents. EHR functionality and design for this purpose is necessary, but effective implementation and use by providers is essential to capturing data that can then be meaningfully shared with external partners in the care of the patient, and used to accurately measure clinical quality.

6. Conclusions

The title of this paper suggests that the transition to C-CDA from HITSP C83 or C32 is a glide path. If this conveys a near effortless and challenge-free activity we have over sold our position. We can say that there is indeed effort, planning, coordination and leadership necessary to achieve the state that is envisioned in Stage 2 MU – a state-broad adoption and use of highly exchangeable, comprehensive, structured clinical summaries. But good work toward the older standard, the HITSP specifications, is mostly progress toward this aim. Our work in 2012 between Beacon Communities, EHR vendors and the ONC has led to improved communication, better understanding of complex technical standards, and significant progress in multiple communities, across multiple vendors, in implementing and using CCD documents.

Our conclusion from this work and our analysis of the C-CDA and Stage 2 MU requirements are:

1. Implementation of HITSP C83 has put us on track headed in same direction as Stage 2 MU and C-CDA. While the C-CDA will be more comprehensive and better specified, the C83 work is an important start with reusable elements, including both content and transport (connectivity).
2. Beacons, HIEs and similar centralized community infrastructures that currently receive a C83 for contribution to a clinical repository or disease registry will need to prepare to transition to C-CDA and to support both C83 and C-CDA document exchanges during a transition period of up to two years.
3. Advancements in coded terminology (vocabulary) requirements in the C-CDA and Stage 2 MU will influence EHR designs for 2014 and beyond, and will have implications on Beacon and HIE data systems and historical analytics.
4. The well-connected healthcare community is best achieved by a collaboration of healthcare providers, EHR vendors, and HIEs. The Beacon EHR AG demonstrated the value of such collaboration and continuous communication. Recognizing that vendors do not have the resources to engage separately with every community or marketplace toward slightly different outcomes, it is important that community aspirations and approaches align well with MU requirements and standards. Communities can then focus on accelerated adoption and use of these standards.

7. Links to Resources

ONC Beacon Communities Program:

- <http://www.healthit.gov/policy-researchers-implementers/beacon-community-program>

Consolidated CDA resources:

- HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates (U.S. Realm)
 - http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
- The S&I Framework's Companion Guide to Consolidated CDA for Meaningful Use
 - ([http://wiki.siframework.org/Companion+Guide+to+Consolidated+CDA+for+Stage 2 MU](http://wiki.siframework.org/Companion+Guide+to+Consolidated+CDA+for+Stage+2+MU))
- Lantana Consulting Group C-CDA Validator
 - <http://www.lantanagroup.com/validator/connectathon.jsp>
- NIST MU2 Validator
 - <http://hit-testing.nist.gov:9100/ttt/>
- Keith Boone's Blog (great resource for up to date information on C-CDA and MU2)
 - <http://www.motorcycleguy.blogspot.com>
- Open Health Tools
 - <http://www.openhealthtools.org/>
- Integrating the Healthcare Enterprise (IHE)
 - <http://www.ihe.net/>
- Healthcare Information Technology Standards Panel (HITSP)
 - C32
Specification: http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32
 - C83
Specification: http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=83

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Bangor Beacon Community
Beacon Community of the Inland Northwest
Central Indiana Beacon Community
Colorado Beacon Consortium
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San Diego Beacon Community
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