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Continuity of Care (CCD) Standards Action Plan

Lantana Consulting Group

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By
Lantana Consulting Group

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U.S. Department of Commerce
Rebecca M. Blank, Acting Secretary

National Institute of Standards and Technology
Patrick D. Gallagher, Under Secretary for Standards and Technology and Director

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CONSULTING GROUP

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Lantana Consulting Group
PO Box 177
East Thetford, VT 05043
www.lantanagroup.com

Liora Alschuler
Chief Executive Officer
liora.alschuler@lantanagroup.com

Bob Dolin, MD, FACP
President and Chief Medical Officer
bob.dolin@lantanagroup.com

Lauren Wood, Ph.D.
Senior Project Manager
lauren.wood@lantanagroup.com

Gaye Dolin, RN, MSN
Senior Nurse Informaticist
gaye.dolin@lantanagroup.com

Jingdong Li, MD
Chief Architect
jingdong.li@lantanagroup.com

Yan Heras
Senior Medical Informaticist
yan.heras@lantanagroup.com

Bob Yencha
Principal Consultant
bob.yencha@lantanagroup.com

Susan Hardy
Senior Technical Editor
susan.hardy@lantangroup.com

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This document is the action plan to improve the suitability of Health Level Seven (HL7) Continuity of Care Document (CCD) to support the Department of Health and Human Services' Stage 1 Meaningful Use (MU). Lantana Consulting Group prepared this report for the National Institute of Standards and Technology (NIST) to accompany the related "CCD Suitability Analysis".

We believe that CCD addresses its intended purpose to provide a snapshot in time of a patient's pertinent clinical, demographic, and administrative data. We believe CCD—with its underlying, stable HL7 Clinical Document Architecture (CDA) standard—will support the overall Meaningful Use goal of achieving significant improvements in care. In our analysis, we identified improvements in testability, testing and validation, error handling, and certification that can enhance the adoption of CCD. In addition, improved documentation from the CDA Consolidation project will mitigate some of the problems presented by layered C32 and Integrating the Healthcare Environment (IHE) constraints. In this document, we recommend actions to address these improvements.

We recognize that testability, testing, and validation will benefit from the investment of software development and policy decisions. There is work to be done to enrich an already strong standard by improving tools and processes. If acted upon, these recommendations will improve CCD's ability to support Meaningful Use.

This document is the action plan to improve the suitability of Health Level Seven (HL7) Continuity of Care Document (CCD) to support the Department of Health and Human Services' Stage 1 Meaningful Use. Lantana Consulting Group prepared this report for the National Institute of Standards and Technology (NIST) to accompany the related "CCD Suitability Analysis"[1].

This plan contains recommended actions for all issues identified in the "CCD Suitability Analysis". We also consider the interdependence between the recommended actions. Resolution of these issues will enrich an already strong standard by improving tools and processes to encourage more widespread adoption of the CCD standard.

We do not duplicate our analysis in this document, but do refer to it wherever applicable. This report does not discuss assignment of responsibility for management of change process.

Any mention of commercial products or organizations in this report is for information only; it does not imply recommendation or endorsement by Lantana or NIST.

1 Both CCD reports were prepared under contract SB134110CN0085.

We recommend five categories of actions: testability, testing and validation, error handling, certification, and documentation. Testability will be improved as model-driven Clinical Document Architecture (CDA) development techniques—such as those described in "Templated CDA: Key Concept for Interoperability"[2] —evolve. Model-driven development will improve our ability to generate Schematron and other testing and validation artifacts. Improved error handling processes will help ensure that errors are corrected at the source, such that revisions cascade to all down-stream artifacts. Certification of implementers in CCD as well as CDA will improve the consistency of technical implementations. Improved documentation, particularly the creation of an implementation guide that flattens the multiple layers of indirection across multiple documents, can dramatically lower the learning curve.

Testability

Testability of the CCD standard will be improved by refining its conformance statements as recommended in the "CCD Coverage Report"[3] and by creating a template library as described in "Templated CDA: Key Concept for Interoperability". We recommend the following actions:

- Re-write CCD conformance statements into multiple, discrete conformance statements with a consistent style, each of which are individually testable.
- Develop a standard style of prose guidance when discrete testable conformance statements require additional guidance for untestable, real-world requirements.
- Create a computable template library.

The CDA Consolidation Project[4] is addressing issues with conformance and testability. If CCD adopts this consistent approach, it will simplify the definition of what is testable and the requirements for validation and run-time validation versus certification.

Templated CDA is a key technology underlying CCD and other HL7 CDA implementation guides. Such template libraries support both standards development and implementation. A template library will improve quality assurance, consistency, and Schematron testing.

Testability and testing improvements will develop hand-in-hand when conformance statements are written with discrete, computable, testable syntax.

Testing and Validation

Schematron validates syntax at several different levels of syntactic correctness. Implementers rely on Schematron to determine the correctness of a CCD instance generation. A better review process for Schematron rule development and the creation of a reference implementation will improve testing and validation. We recommend the following actions:

2 Lantana Consulting Group. Templated CDA: Key Concept for Interoperability, May 2011. Related document prepared for NIST.
3 Lantana Consulting Group. CCD Coverage Report, May 2011. Related document prepared for NIST.
4 http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project

- Develop and publish Schematron rules along with the CCD standard revisions. Any off-the-shelf XML tool can then apply these Schematron rules to validate CCD instances.
- Establish a healthcare information technology (HIT) community review and consensus process as part of the development of Schematron rules, so that they can be publicly vetted.
- Consider using other testing technologies to improve instance testing as identified in the "CCD Coverage Report", such as model-driven validation and RELAX NG.
- Create a CCD reference implementation. A reference implementation could be built to the current specification; it should then be enhanced with subsequent CCD versions as part of testing and validation of new or versioned templates.
- Improve vocabulary validation. When a system receives a CCD instance, it must validate the structural correctness of the instance and whether a correct code is received for a coded data element. Codes from dynamic vocabulary bindings are difficult to validate and require interface with terminology services. Health care often uses dynamic value sets to support new knowledge and to supply missing terms. A single, go-to terminology service such the *HL7 Version 3 Standard: Common Terminology Services, DSTU Release 2)*[5] would mitigate this testing problem. See the "CCD Coverage Report" for a full discussion of this issue.

Error Handling

HL7 has a well-defined error-handling system. Errors for base CCD are handled within the HL7 community on errata pages and by the Structured Document Work Group meetings. We recommend creation of a coordinated cross-organization error handling process for C32.

Certification

HL7 provides one type of certification for the professionals who work with the CDA, but there is no certification for CCD. We recommend the following actions:

- Create a certification for proficiency in CCD/C32.
- Create several depths to the certification program so that it can be tailored to different roles/job types.

Certification overlaps with all recommendations in that updates in the CCD standard and related tools will have to be reflected in any certification programs.

Documentation

CCD/C32 places multiple layers of constraints on top of CCD and presents a barrier to adoption. We recommend flattening that stack and improving its documentation to present a single resource for implementers of CCD/C32:

- Reconcile (resolve ballot comments) and publish the HL7 CDA Consolidated Implementation Guide (currently in ballot).

5 HL7 Version 3 Standard: Common Terminology Services, DSTU Release 2
http://www.hl7.org/documentcenter/public/standards/dstu/2009may/V3_CTS_R2_DSTU_2009OCT.pdf

- Harmonize discrepancies across HL7, IHE, and Healthcare Information Technology Standards Panel (HITSP) and ballot the remaining CCD/C32 and applicable C83 modules in version 2 of the HL7 CDA Consolidated Implementation Guide.
- Ensure template changes are tracked and noted so implementers can quickly locate where changes need to be made in existing CCD/C32 implementations.
- Augment the HL7/IHE Health Story Consolidation Project with new templates supporting new use cases and common document types.

The CCD standard fulfills its purpose and satisfies the criteria we defined for suitability for Meaningful Use. CCD is robust because of the underlying well-accepted HL7 CDA standard and the ability to represent data elements in a consistent manner through vetted templates. The actions identified in this plan, if implemented, will further strengthen the standard, increase the rate of implementation, and prepare it for the future.

Testability, testing, and validation will require an investment of software development and policy decisions. Authoring and testing tools are in development, but need to be enhanced and to mature to meet all of the HIT standards industry needs for CCD and other CDA implementation guides. Development of a single CCD/C32 resource for implementers is in progress; it requires the participation and support of stakeholders to see the project through to completion. A process for error handling inclusive of C32 requires cross-organization policy and process coordination.

In summary, these steps can enrich an already strong standard by improving tools and processes to increase its validity and reliability in communicating patient information in a uniform, consistent manner between healthcare organizations.

- CDA Consolidation Project. http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project
- HL7 Version 3 Standard: Common Terminology Services, DSTU Release 2 http://www.hl7.org/documentcenter/public/standards/dstu/2009may/V3_CTS_R2_DSTU_2009OCT.pdf
- Department of Health and Human Services. *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule*, 45 CFR Part 170. http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf
- Department of Health and Human Services. *Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule – Stage 1 Meaningful Use Objectives*, 42 CFR Parts 412, 413, 422 et al. http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf
- *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD):* A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR) April 01, 2007 available through HL7: http://www.hl7.org
- Lantana Consulting Group. CCD Coverage Report, May 2011. Related document prepared for NIST.
- Lantana Consulting Group. Continuity of Care Document (CCD) Suitability Analysis, May 2011. Related document prepared for NIST.
- Lantana Consulting Group. Templated CDA: Key Concept for Interoperability, May 2011. Related document prepared for NIST.
- The S&I Framework Initiative: CDA Consolidation Project. http://wiki.siframework.org/CDA+Harmonization+WG

Acronyms and Abbreviations

CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
HIT	Healthcare Information Technology
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
IHE	Integrating the Healthcare Environment
IT	Information Technology
MU	Meaningful Use
NIST	National Institute of Standards and Technology