



HL7 CDA® R2 Implementation Guide:
National Healthcare Safety Network (NHSN)
Healthcare Associated Infection (HAI) Reports for
Long Term Care Facilities,
Release 1, STU 3 - US Realm
HL7 Standard for Trial Use (STU) Ballot
Volume 1—Introductory Material

Specification Date: May 2025

Specification Version: 1.3 May 2025

Sponsored by:
Public Health Work Group
Structured Documents (SD) Work Group
National Healthcare Safety Network (NHSN)

Copyright © 2025 Health Level Seven International ® ALL RIGHTS RESERVED. The reproduction of this material in any form is strictly forbidden without the written permission of the publisher. HL7 and Health Level Seven are registered trademarks of Health Level Seven International. Reg. U.S. Pat & TM Off. Use of this material is governed by HL7's [IP Compliance Policy](#).

IMPORTANT NOTES:

HL7 licenses its standards and select IP free of charge. **If you did not acquire a free license from HL7 for this document**, you are not authorized to access or make any use of it. To obtain a free license, please visit <http://www.HL7.org/implement/standards/index.cfm>.

If you are the individual that obtained the license for this HL7 Standard, specification or other freely licensed work (in each and every instance "Specified Material"), the following describes the permitted uses of the Material.

A. HL7 INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS, who register and agree to the terms of HL7's license, are authorized, without additional charge, to read, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part without paying license fees to HL7.

INDIVIDUAL, STUDENT AND HEALTH PROFESSIONAL MEMBERS wishing to incorporate additional items of Special Material in whole or part, into products and services, or to enjoy additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS as noted below, must become ORGANIZATIONAL MEMBERS of HL7.

B. HL7 ORGANIZATION MEMBERS, who register and agree to the terms of HL7's License, are authorized, without additional charge, on a perpetual (except as provided for in the full license terms governing the Material), non-exclusive and worldwide basis, the right to (a) download, copy (for internal purposes only) and share this Material with your employees and consultants for study purposes, and (b) utilize the Material for the purpose of developing, making, having made, using, marketing, importing, offering to sell or license, and selling or licensing, and to otherwise distribute, Compliant Products, in all cases subject to the conditions set forth in this Agreement and any relevant patent and other intellectual property rights of third parties (which may include members of HL7). No other license, sublicense, or other rights of any kind are granted under this Agreement.

C. NON-MEMBERS, who register and agree to the terms of HL7's IP policy for Specified Material, are authorized, without additional charge, to read and use the Specified Material for evaluating whether to implement, or in implementing, the Specified Material, and to use Specified Material to develop and sell products and services that implement, but do not directly incorporate, the Specified Material in whole or in part.

NON-MEMBERS wishing to incorporate additional items of Specified Material in whole or part, into products and services, or to enjoy the additional authorizations granted to HL7 ORGANIZATIONAL MEMBERS, as noted above, must become ORGANIZATIONAL MEMBERS of HL7.

Please see <http://www.HL7.org/legal/ippolicy.cfm> for the full license terms governing the Material.

Ownership. Licensee agrees and acknowledges that **HL7 owns** all right, title, and interest, in and to the Materials. Licensee shall **take no action contrary to, or inconsistent with**, the foregoing.

Licensee agrees and acknowledges that HL7 may not own all right, title, and interest, in and to the Materials and that the Materials may contain and/or reference intellectual property owned by third parties ("Third Party IP"). Acceptance of these License Terms does not grant Licensee any rights with respect to Third Party IP. Licensee alone is responsible for identifying and obtaining any necessary licenses or authorizations to utilize Third Party IP in connection with the Materials or otherwise. Any actions, claims or suits brought by a third party resulting from a breach of any Third Party IP right by the Licensee remains the Licensee's liability.

Following is a non-exhaustive list of third-party terminologies that may require a separate license:

Terminology	Owner/Contact
Current Procedures Terminology (CPT) code set	American Medical Association https://www.ama-assn.org/practice-management/cpt-licensing
SNOMED CT®	SNOMED CT® International; http://www.snomed.org/snomed-ct/get-snomed-ct or info@ihtsdo.org
Logical Observation Identifiers Names & Codes (LOINC®)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
NUCC Health Care Provider Taxonomy code set	American Medical Association. Please see www.nucc.org . AMA licensing contact: 312-464-5022 (AMA IP services)

Obtaining a CPT Sublicense from HL7

Contact hq@hl7.org about how to obtain a sublicense from HL7 for non-production use of CPT for (i) the development and publication of value sets, profiles, and other artifacts as part of the HL7 Implementation Guides, (ii) as part of defined VSAC value sets, and (iii) to support HL7's terminology services within the Territory.

Flow Down Clauses for CPT Sublicense from HL7

CPT content is copyrighted by the American Medical Association and CPT is a registered trademark of the AMA.

HL7, as a party to a license agreement with the AMA, is authorized to grant user a limited, non-exclusive, non-transferable, non-sublicensable license for user to use CPT content for (i) the development and publication of value sets, profiles, and other artifacts as part of the HL7 Implementation Guides, (ii) as part of defined VSAC value sets, and (iii) to support HL7's terminology services within the Territory, each of which shall be considered a non-production use. The sublicense granted hereunder shall automatically terminate upon termination of the agreement between HL7 and AMA, unless prior written consent of AMA is obtained.

The provision of updated CPT content is dependent on a continuing contractual relationship between HL7 and the AMA.

User acknowledge a separate license agreement shall be required, and shall govern any proposed use, including any distribution of CPT content for any other purposes not expressly permitted under this Agreement, and the terms of such agreement will govern such use (e.g., a separate license agreement shall govern production use and commercial purposes). AMA reserves the right to accept or reject licenses based on AMA's evaluation of the proposed use of the CPT content.

User acknowledge that User's development and commercialization of CPT-informed works developed with reference to Licensed Products may only be implemented in the Territory.

User is prohibited from making CPT content publicly available, creating derivative works (including translating), transferring, selling, leasing, licensing, or otherwise making available to any unauthorized party the CPT content, or a copy or portion of CPT content to any unauthorized party, including a subsidiary, affiliate, or other legal entity, however designated, for any purpose whatsoever except as expressly permitted under a separate agreement.

User expressly acknowledges and agrees to the extent permitted by applicable law, use of CPT content is at User's sole risk and CPT content is provided "as is" without warranty of any kind. The AMA does not directly or indirectly practice medicine or dispense medical services. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. CPT content herein does not replace the AMA's Current Procedural Terminology book or other appropriate coding authority. The coding information contained in CPT content should be used only as a guide.

U.S. Government End Users. CPT is commercial technical data, which was developed exclusively at private expense by the American Medical Association (AMA), 330 North Wabash Avenue, Chicago, Illinois 60611. This agreement does not grant the Federal Government a direct license to use CPT based on FAR 52.227- 14 (Data Rights - General) and DFARS 252.227-7015 (Technical Data - Commercial Items).

User expressly consents to the release of its name to the AMA.

Structure of This Guide

Two volumes comprise the complete *HL7 CDA® R2 Implementation Guide: NHSN Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (HAI-LTCF-CDA)*. Volume 1 provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2. Volume 2 contains the normative Clinical Document Architecture (CDA) templates for this guide along with lists of all templates, code systems, value sets, and, when appropriate, changes from the previous version.

Primary Editor:	Zabrina Gonzaga Lantana Consulting Group zabrina.gonzaga@lantanagroup.com	Primary Editor:	Dave deRoode Lantana Consulting Group david.deroode@lantanagroup.com
Primary Editor:	Sarah Gaunt Lantana Consulting Group sarah.gaunt@lantanagroup.com	SD Co-Chair:	Gaye Dolin M.S.N., R.N. Namaste Informatics mgdolin@namasteinformatics.com
SD Co-Chair:	Austin Kreisler Leidos Consultant to CDC/NHSN duz1@cdc.gov	SD Co-Chair:	Benjamin Flessner Avality benjamin.flessner@avality.com
SD Co-Chair:	Russell Ott Deloitte Consulting LLP rott@deloitte.com	Co-Chair:	Matt Szczepankiewicz Epic mszczepa@epic.com
Co-Chair:	Joanne Dehnbostel MPH, MSc Computable Publishing LLC jdehnbostel@computablepublishing.com	Co-Chair:	Erin Holt, MPH Tennessee Department of Health erin.holt@tn.gov
Co-Chair:	Craig Newman Altarum craig.newman@altarum.org	Co-Chair:	Danny Wise Allscripts danny.wise@allscripts.com
Co-Chair:	Ravi Kafle Washington State Department of Health ravi.kafle@doh.wa.gov	Co-Chair:	Forrest White Altarum forrest.white@altarum.org
Co-Editor:	Jeneita Bell, MD, MPH CDC Hpg8@cdc.gov	Co-Editor:	Andrea Benin CDC aqb4@cdc.gov
Co-Editor:	Angella Antilla, PhD, MSN CDC vtb9@cdc.gov	Co-Editor:	Sylvia Shuler CDC mfub3@cdc.gov
Co-Editor:	Sheri Chernetsky Tejedor, MD CDC yei9@cdc.gov	Co-Editor:	Sheila Abner CDC sha8@cdc.gov
Co-Editor:	Sami Petersen Lantana Consulting Group samantha.petersen@lantanagroup.com	Co-Editor:	Liora Alschuler Lantana Consulting Group liora.alschuler@lantanagroup.com
Technical Editor:	Diana Wright Lantana Consulting Group diana.wright@lantanagroup.com		
Stakeholder contributors: Cerner: Cindy Frakes, Steve Herron, Jamie Gatzke, Kelly Luden, Prasath Govindarajulu; Point Click Care: Laura Ditz, Nancy Chi, Nichole (Nicki) Fetterman, Michael Furman, Patti Barton, Aga Lee; NASL: Donna Doneski; Matrix Care: Denise Wassenaar, Doc DeVore, Rob Price			

Acknowledgments

This implementation guide was produced and developed by Lantana Consulting Group in conjunction with the Division of Healthcare Quality Promotion in the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) at the Centers for Disease Control and Prevention (CDC). Its development is a result of the dedication of the team—led by Daniel A. Pollock, M.D., Surveillance Branch Chief, Division of Healthcare Quality Promotion, NCEZID, CDC and Jeneita Bell, MD, MPH, Long-term Care Team

Lead, DHQP, NCEZID, CDC—and their support of the development of interoperable data standards for the CDC’s National Healthcare Safety Network (NHSN).

This standard is a set of constraints on existing work, and the extent to which it can accommodate the expressive requirements of HAI reporting over time is a function of the richness of the model on which it is built, the Health Level Seven (HL7) Reference Information Model (RIM) and the RIM document standard, and the Clinical Document Architecture Release 2 (CDA R2). We thank all those who have worked for over a decade to produce these fundamental standards.

This material contains content from SNOMED CT® (<http://www.ihtsdo.org/snomed-ct/>). SNOMED CT is a registered trademark of the International Health Terminology Standard Development Organisation (IHTSDO).

This material contains content from LOINC® (<http://loinc.org>). The LOINC table, LOINC codes, and LOINC panels and forms file are copyright © 1995-2019, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and available at no cost under the license at <http://loinc.org/terms-of-use>.

Revision History

Release	Date	Notes
STU 1	September 2019	First release of the STU
STU 1.1	February 2023	First unballoted update of the STU
STU 1.2	March 2024	First update of the first STU
STU 2	September 2024	Second release of the STU
STU 3	May 2025	Ballot for third release of the STU

Table of Contents

Obtaining a CPT Sublicense from HL7	2
Flow Down Clauses for CPT Sublicense from HL7	2
STRUCTURE OF THIS GUIDE	4
ACKNOWLEDGMENTS.....	5
REVISION HISTORY.....	6
TABLE OF CONTENTS	7
FIGURES	9
TABLES	10
1 INTRODUCTION.....	11
NOTE TO BALLOTTERS—ITEMS FOR VOTING	11
1.1 Purpose.....	11
1.2 Relationship to Another Standard.....	12
1.3 Audience	12
1.4 Organization of the Guide (Volumes 1 and 2).....	12
1.4.1 Volume 1 Introductory Material	13
1.4.2 Volume 2 CDA Templates and Supporting Material	13
1.4.3 Example Instance Identifiers	14
1.5 Contents of the Package	14
2 CDA AND NHSN HAI LTCF REPORTING.....	16
2.1 CDA R2 Background	16
2.2 Templated CDA	16
2.3 LTCF HAI Reporting Background.....	17
2.4 Current Release.....	17
2.5 Change Notification Process	18
3 DESIGN CONSIDERATIONS.....	19
3.1 Rendering Header Information for Human Presentation.....	19
3.2 Unknown and No Known Information	19
3.3 Negating Clinical Statements.....	23
3.4 Summary Document serviceEvent Codes.....	23
4 USING THIS IMPLEMENTATION GUIDE	24
4.1 Levels of Constraint.....	24

4.2	Conformance Conventions Used in This Guide	24
4.2.1	Templates and Conformance Statements	24
4.2.2	Template Versioning.....	26
4.2.3	Open and Closed Templates.....	27
4.2.4	Conformance Verbs (Keywords)	27
4.2.5	Cardinality	27
4.2.6	Optional and Required with Cardinality	28
4.2.7	Vocabulary Conformance	28
4.2.8	Data Types.....	30
4.2.9	Succession Management	30
4.3	XML Conventions Used in This Guide.....	30
4.3.1	XPath Notation.....	30
4.3.2	XML Examples and Sample Documents	31
4.4	Supporting Tools	31
4.4.1	Validation	31
4.4.2	Generation of Narrative Block	32
4.4.3	Display Transforms.....	32
5	REFERENCES.....	33
APPENDIX A —	ACRONYMS AND ABBREVIATIONS.....	34
APPENDIX B —	HIGH-LEVEL CHANGES FROM PREVIOUS RELEASES.....	35
	3rd HL7 Standard for Trial Use (STU)	35
	2nd HL7 Standard for Trial Use (STU).....	35
	2nd Update to 1st HL7 Standard for Trial Use (STU)	35
	1st Update to 1st HL7 Standard for Trial Use (STU)	36
APPENDIX C —	DOCUMENT AND SECTION CODES (NON-NORMATIVE).....	37
APPENDIX D —	CONSOLIDATED CDA (C-CDA) TEMPLATES REFERENCED IN THIS GUIDE	38
APPENDIX E —	EXAMPLE INSTANCE IDENTIFIERS (NON-NORMATIVE)	39
APPENDIX F —	VOCABULARY HEURISTICS FOR CODES AND VALUE SETS (NON- NORMATIVE)41	
	Code and codeSystem Selection	41
	Value Set Assignment and Maintenance	41

Figures

Figure 1: Templated CDA	16
Figure 2: nullFlavor Example	20
Figure 3: Attribute Required—nullFlavor not allowed	20
Figure 4: Allowed nullFlavors When Element is Required—with XML examples	21
Figure 5: Unknown Medication Example	21
Figure 6: Unknown Medication Use of Anticoagulant Drug Example	22
Figure 7: No Known Medications Example.....	22
Figure 8: Value Known—code for value not known	22
Figure 9: Value Completely Unknown	23
Figure 10: Value Known—code in required code system not known but code from another code system is known.....	23
Figure 11: Context Table Example.....	25
Figure 12: Constraints Overview Table Example.....	25
Figure 13: Constraints Format Example.....	26
Figure 14: Constraints Format—only one allowed	28
Figure 15: Constraints Format—only one like this allowed	28
Figure 16: Binding to a Single Code	29
Figure 17: XML Expression of a Single-code Binding.....	29
Figure 18: Example Value Set Table	30
Figure 19: XML Document Example	31
Figure 20: XPath Expression Example	31
Figure 21: ClinicalDocument Example	31

Tables

Table 1: Contents of the Package – Normative & Informative	14
Table 2: GitHub Contents – Informative Only	15
Table 3: Document and Section Codes	37
Table 4: C-CDA Template OIDs	38
Table 5: Structure of Example OIDs	39
Table 6: Values of Example Instance Identifiers Used in This Guide	40

1 INTRODUCTION

Note to Balloters—Items for Voting

This note will be removed in the published version of the implementation guide (IG).

This ballot contains two volumes. Volume 1 contains the guide’s introductory material and Volume 2 contains the templates. Below are descriptions of items that may be voted on in each volume.

Volume 1:

- The body of the document up until the appendices **MAY** be voted on.

Volume 2:

- Templates that are new or revised are signified by the wording “Draft as part of ...” below the template name. **These MAY be voted on.**

EXAMPLE:

HAI Single-Person Report Generic Constraints LTCF (V4)

[ClinicalDocument: identifier
urn:hl7ii:2.16.840.1.113883.10.20.5.1.1.3:2024-05-01 (open)]

Draft as part of NHSN Healthcare Associated Infection (HAI)
Report for Long Term Care Facilities (LTCF), Release 1, STU 2 -
US Realm

- Templates that have been brought in unchanged from a previous release are signified by the wording “Published as part of NHSN Healthcare Associated Infection (HAI) Reports ...” below the template name. **These MAY NOT be voted on.**

EXAMPLE:

HAI Section Generic Constraints

[section: identifier urn:oid:2.16.840.1.113883.10.20.5.4.26
(closed)]

Published as part of NHSN Healthcare Associated Infection (HAI)
Reports Release 1 - US Realm

1.1 Purpose

This implementation guide (IG) specifies standards for electronic submission of Healthcare Associated Infection (HAI) reports to the National Healthcare Safety Network (NHSN) of the Centers for Disease Control and Prevention (CDC) for Long Term Care Facilities (LTCFs). This IG contains an overview of CDA markup standards, design, and use (Volume 1) and a library of CDA templates for electronic submission of HAI reports to the NHSN from LTCFs (Volume 2). As reports are modified and new report types are

defined, CDC and Health Level Seven (HL7) will develop and publish additional constraints.

Throughout this process, CDC remains the authority on NHSN data collection protocols. When healthcare enterprises choose to participate in NHSN, they must report to CDC reportable events such as identified MDRO (multidrug-resistant organism) or CDI (*C. difficile* infection). This standard opens the channel for data submission by all applications compliant with the data coding requirements defined in this guide.

Note that participation in the NHSN requires enrollment and filing of reporting plans, which are not defined by this standard. For an overview of NHSN and full information on NHSN participation requirements, see: <http://www.cdc.gov/nhsn>. Provisions of the Public Health Service Act protect all data reported to NHSN from discovery through the Freedom of Information Act (FOIA).

1.2 Relationship to Another Standard

HL7 has developed a Fast Healthcare Interoperability Resources (FHIR) IG in parallel with this CDA IG. We anticipate several Standard for Trial Use (STU) releases on the path to a Normative Release 1 of the *HL7 Implementation Guide for CDA and FHIR for Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (HAI-LTCF-CDA)*. The FHIR and CDA IGs will align. A change to one standard will require the same change in the other standard.

In this release, the Laboratory-identified MDRO or CDI Event for LTCF, Denominators for LTCF, MDRO and CDI Monthly Monitoring for LTCF, and Prevention Process Measures Forms are included in both the CDA and FHIR standards. For further details see the NHSN website for reporting healthcare-associated infections in long-term care facilities¹.

1.3 Audience

The audience for this work is all developers of software systems who want to enable their systems to report HAI data to the NHSN.

1.4 Organization of the Guide (Volumes 1 and 2)

This *HL7 CDA® R2 Implementation Guide: NHSN Healthcare Associated Infection (HAI) for Long Term Care Facilities (HAI-LTCF-CDA)* is organized into two volumes:

- Volume 1 contains primarily narrative text describing the HAI-LTCF-CDA guide.
- Volume 2 contains CDA template definitions.

¹ NHSN Website. <https://www.cdc.gov/nhsn/>

1.4.1 Volume 1 Introductory Material

This document, Volume 1, provides an overview of Clinical Document Architecture (CDA), recent changes to the standard, and information on how to understand and use the CDA templates provided in Volume 2.

- **Chapter 1—Introduction**
- **Chapter 2—CDA and NHSN HAI LTCF Reporting** contains project background and selected background material on the CDA R2 base standard to aid the reader in conceptualizing the “templated CDA” approach to IG development.
- **Chapter 3—Design Considerations** describes overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as “heuristics”, as opposed to the formal and testable constraints found in Volume 2 of this guide.
- **Chapter 4—Using This Implementation Guide** describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.
- **Chapter 5—References** lists documents and sources cited by this guide.
- **Appendices** include acronyms and abbreviations, a list of codes used by NHSN HAI LTCF reports, a list of Consolidated CDA (C-CDA) templates to which HAI LTCF templates conform, example instance identifiers, and vocabulary heuristics for code systems and value sets.

1.4.2 Volume 2 CDA Templates and Supporting Material

Volume 2 includes CDA templates and prescribes their use for a set of specific document types. The main chapters are:

- **Chapter 1—Document-Level Templates** defines the report requirements for all CDA documents for HAI reporting from LTCFs.

The NHSN HAI LTCF report requirements apply to constraints on the CDA header and sections and include the requirement that the body be represented by a `structuredBody` element.

The header requirements for population summary reports and for single-person reports differ significantly. HAI defines a generic header template for each of these two sets of requirements. Report-specific templates give additional requirements for each report type in this IG.
- **Chapter 2—Section-Level Templates** defines the generic constraints that apply to all sections along with specific requirements for each section used by the NHSN HAI LTCF reports in this guide.
- **Chapter 3—Entry-Level Templates** defines clinical statements. Machine processable data are sent in the entry templates. The entry templates are referenced by one or more section templates. Entry-level templates are always contained in section-level templates, and section-level templates are always contained in a document. Requirements for all entries (including organizers) used by the reports in this guide are in alphabetical order.

- **Chapter 4—Template IDs in This Guide** lists the template identifiers used by this guide for HAI reporting from LTCFs to NHSN. These template identifiers are assigned at the document, section, and entry level. Tables list NHSN templates by type and name and by containment. (Consolidated CDA R2.1 templates to which the NHSN templates conform are listed in Volume 1.)
- **Chapter 5—Value Sets in This Guide** lists all value set names and object identifiers (OIDs) used by HAI templates. Links are provided to external value set sources if appropriate.
- **Chapter 6—Code Systems in This Guide** lists all code system names and OIDs used by LTCF HAI templates, both for value sets and single-value bindings.

1.4.3 Example Instance Identifiers

Much of the initial development of this guide was driven by a pilot project in July 2007. The pilot project used OIDs assigned to a fictional facility and vendor to illustrate the numbering schemes for which facilities and vendors are responsible.

Except for the example resident identifiers, the example code in this document and the accompanying sample files use these pilot OIDs. Example resident identifiers use the HL7 example OID. In practice, the identifiers will be assigned by facilities and software applications submitting reports to NHSN.

These pilot instance identifiers begin with 2.16.840.1.113883.3.117.1.1.5; HL7 example identifiers begin with 2.16.840.1.113883.19.5. They are used throughout this guide and are documented in the appendix on [Example Instance Identifiers \(Non-normative\)](#).

1.5 Contents of the Package

The following files comprise this package.

Table 1: Contents of the Package – Normative & Informative

Filename	Description	Informative
CDAR2_IG_HAI_LTCF_R1_STU3_V1_Introductory_Material.docx	Vol 1: Introductory material for this implementation guide	Chapter 2 Chapter 3 Chapter 5
CDAR2_IG_HAI_LTCF_R1_STU3_V2_Templates_and_Supporting.docx	Vol 2: CDA templates for this implementation guide	
CDAR2_IG_HAI_LTCFRPT_R1_STU3_LabIDEvent.xml	Sample file for HAI Laboratory Identified MDRO or CDI Event Report for LTCF	Examples
CDAR2_IG_HAI_LTCFRPT_R1_STU3_LabIDSummary.xml	Sample file for MDRO and CDI LabID Event Reporting Monthly Summary Data for LTCF	

CDAR2_IG_HAI_LTCF_R1_STU3.sch	Schematron rules	
CDAR2_IG_HAI_LTCF_R1_STU3.xml	Value set and code system resource	
hai-display.xsl	Stylesheet for rendering	
nhsnlogo_small.gif	NHSN logo	

Table 2: GitHub Contents – Informative Only

Filename	Description
Sample files	
CDAR2_IG_HAI_LTCFRPT_R1_STU3_LabIDEvent.xml	Sample file for HAI Laboratory Identified MDRO or CDI Event Report for LTCF
CDAR2_IG_HAI_LTCFRPT_R1_STU3_LabIDSummary.xml	Sample file for MDRO and CDI LabID Event Reporting Monthly Summary Data for LTCF
CDAR2_IG_HAI_LTCF_R1_STU3.sch	Schematron rules
CDAR2_IG_HAI_LTCF_R1_STU3.xml	Value set and code system resource
hai-display.xsl	Stylesheet for rendering
nhsnlogo_small.gif	NHSN logo
Support files	
XML and Related files (Schematron, sample, html, stylesheet) are housed on the HL7 GitHub site: https://github.com/HL7/CDA-hai-ltcf/tree/main/CDA-hai-ltcf-1.3	
The latest CDA Schema is located on the HL7 GitHub site: https://github.com/HL7/cda-core-2.0/tree/master/schema/extensions	

2 CDA AND NHSN HAI LTCF REPORTING

2.1 CDA R2 Background

This IG uses the *HL7 Clinical Document Architecture, Release 2.0* as its base standard.² CDA R2 is “... a document markup standard that specifies the structure and semantics of ‘clinical documents’ for the purpose of exchange” [CDA R2, Section 1.1]. Clinical documents, according to CDA, have the following characteristics:

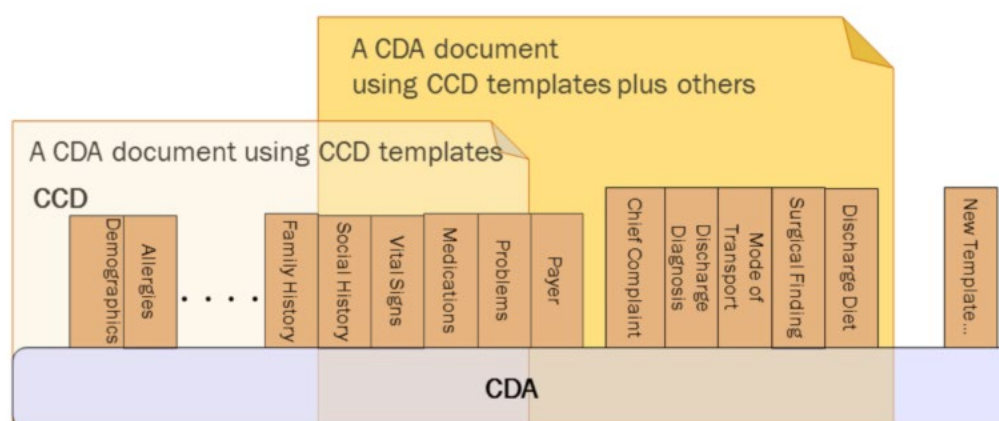
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA defines a header for classification and management, and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

2.2 Templated CDA

CDA R2 can be constrained by mechanisms defined in the “Refinement and Localization”³ section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as “templated CDA”. In this approach, a library is created containing modular CDA templates such that the templates can be reused across any number of CDA document types, as shown in the following figure.

Figure 1: Templated CDA



² HL7 CDA R2. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

³ HL7 V3: Refinement, Constraint and Localization.

<http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm>

Many different kinds of templates may be created. Among them, the most common are:

- **Document-level templates:** These templates constrain fields in the CDA header and define containment relationships to CDA sections. For example, a History and Physical document-level template might require that the resident's name be present, and that the document contain a Physical Exam section.
- **Section-level templates:** These templates constrain fields in the CDA section and define containment relationships to CDA entries. For example, a Physical Exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Systolic Blood Pressure observation.
- **Entry-level templates:** These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic Blood Pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.

A CDA IG (such as this one) includes reference to those templates that are applicable. On the implementation side, a CDA instance populates the template identifier (`templateId`) field to assert conformance to a given template. On the receiving side, the recipient can not only test the instance for conformance against the CDA XML (Extensible Markup Language) schema but can also test the instance for conformance against asserted templates.

Template identifiers are critical to the validation methods chosen for submissions to the NHSN. NHSN may reject nonconformant instances that do not conform to the template identifier constraints defined here.

Please reference the NHSN webpage (<http://www.cdc.gov/nhsn/>) to identify which HAI release NHSN currently supports for a given report type.

2.3 LTCF HAI Reporting Background

LTCF HAI reporting standards were first released in 2012, with data submitted by paper form and manual web entry. The CDA and FHIR standards for electronic HAI reporting from LTCFs will be balloted for the first time in 2019. This CDA IG, and its parallel FHIR IG, will permit LTCFs to submit standardized surveillance data for public reporting of HAI and other reportable events to NHSN directly from electronic health record (EHR) systems. This method of data collection and submission to NHSN can greatly reduce reporter burden and improve work efficiency. It is also expected that data errors may decrease, thereby improving data quality for national benchmarks, monitoring trends, and measuring progress towards infection prevention goals. Going forward as this IG will likely be updated and expanded every year, it will continue to go through the HL7 ballot comment and reconciliation process each time.

2.4 Current Release

This IG is the third STU release of the LTCF HAI reporting templates. The following changes were made:

- Update HAI Single Person Report Generic Constraints LTCF to:

- Remove and prohibit patient/administrativeGenderCode
- Update Laboratory Identified MDRO or CDI Event Report for LTCF (V4) to:
 - Contain the updated NHSN Social History Section (V4) (from NHSN Healthcare Associated Infection Reports):
 - One template was added:
 - Sex (from NHSN Healthcare Associated Infection Reports)
 - Two templates were removed:
 - Gender Identity (C-CDA)
 - Birth Sex (C-CDA)

2.5 **Change Notification Process**

CDC maintains an e-mail list of contacts at organizations interested in or responsible for implementations of CDA for LTCF HAI reporting to NHSN. To be added to the list, send a request with your contact information to nhsncda@cdc.gov. CDC uses the list for e-mail notifications of changes, including new data requirements. Changes may apply to this IG and to other documents such as business rules that are needed to implement and support CDA for LTCF HAI reporting to NHSN. NHSN CDA related information may be found at <https://www.cdc.gov/nhsn/cdaportal/index.html>.

3 DESIGN CONSIDERATIONS

Design considerations describe overarching principles that have been developed and applied across the CDA templates in this guide. Material in this section can be thought of as “heuristics”, as opposed to the formal and testable constraints found in Volume 2 of this guide.

3.1 *Rendering Header Information for Human Presentation*

Metadata carried in the header may already be available for rendering from EHRs or other sources external to the document, therefore, there is no strict requirement to render directly from the document. An example of this would be a doctor using an EHR that already contains the resident’s name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR’s user interface.

Good practice recommends that the following be present whenever the document is viewed:

- Document title and document dates
- Service and encounter types, and date ranges as appropriate
- Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
- Date of birth for `recordTarget(s)`

3.2 *Unknown and No Known Information*

Information may be unknown, not relevant, or not computable or measurable, such as where a resident arrives at an Emergency Department unconscious and with no identification.

In many cases, the CDA standard will stipulate that a piece of information is required (e.g., via a **SHALL** conformance verb). However, in most of these cases, the standard provides an “out”, allowing the sender to indicate that the information isn’t known.

Here, we provide guidance on representing unknown information.

This list contains the null flavors that are commonly used in clinical documents. This list is found in the null flavor vocabulary domain in the HL7 V3 Data Types that accompanies the CDA R2 normative standard⁴.

⁴ *HL7 Vocabulary Domains.*

http://vico.org/CDAR22005_HL7SP/infrastructure/vocabulary/NullFlavor.htm

Use null flavors for unknown, required, or optional attributes, where allowed per the NHSN protocol:

NI	No information. This is the most general and default null flavor.
NA	Not applicable. Known to have no proper value (e.g., last menstrual period for a male).
UNK	Unknown. A proper value is applicable but is not known.
ASKU	Asked, but not known. Information was sought, but not found (e.g., the resident was asked but did not know).
NAV	Temporarily unavailable. The information is not available but is expected to be available later.
NASK	Not asked. The resident was not asked.
MSK	There is information on this item available, but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.
OTH	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).

Figure 2: nullFlavor Example

```
<!-- CDA requires the consumable element, however NHSN does not
collect further information about the antifungal -->
<consumable>
  <manufacturedProduct>
    <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
    <manufacturedMaterial>
      <code nullFlavor="NI"/>
    </manufacturedMaterial>
  </manufacturedProduct>
</consumable>
```

Unless a nullFlavor is explicitly stated in a constraint in the IG, nullFlavors are not allowed.

Figure 3: Attribute Required—nullFlavor not allowed

1. **SHALL** contain exactly one [1..1] code (CONF:15407).
 - a. This code **SHALL** contain exactly one [1..1] @code="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15408).
- or
2. **SHALL** contain exactly one [1..1] effectiveTime/@value (CONF:5256).

Figure 4: Allowed nullFlavors When Element is Required—with XML examples

```
1. SHALL contain at least one [1..*] id
2. SHALL contain exactly one [1..1] code
3. SHALL contain exactly one [1..1] effectiveTime

<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn't know an attribute of an act, that attribute can be null.

Figure 5: Unknown Medication Example

```
<entry>
  <text>resident was given a medication, but I do not know what it was</text>
  <substanceAdministration moodCode="EVN" classCode="SBADM">
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code nullFlavor="NI"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

2. If the sender doesn't know if an act occurred, the nullFlavor is on the act (detail could include specific allergy, drug, etc.).

Figure 6: Unknown Medication Use of Anticoagulant Drug Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
    <text>I do not know whether or not resident received an anticoagulant
      drug</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="81839001" displayName="anticoagulant drug"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

3. If the sender wants to state, "no known", a negationInd can be used on the corresponding act (substanceAdministration, Procedure, etc.)

Figure 7: No Known Medications Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" negationInd="true">
    <text>No known medications</text>
    <consumable>
      <manufacturedProduct>
        <manufacturedLabeledDrug>
          <code code="410942007" displayName="drug or medication"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"/>
        </manufacturedLabeledDrug>
      </manufacturedProduct>
    </consumable>
  </substanceAdministration>
</entry>
```

These next examples illustrate additional nuances of representing unknown information in coded fields.

Figure 8: Value Known—code for value not known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    ...
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 9: Value Completely Unknown

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    ...
    <value xsi:type="CD" nullFlavor="UNK"/>
  </observation>
</entry>
```

Figure 10: Value Known—code in required code system not known but code from another code system is known

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    ...
    <value xsi:type="CD" nullFlavor="OTH">
      <originalText>Spiculated mass grade 5</originalText>
      <translation code="129742005" displayName="spiculated lesion"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT"/>
    </value>
  </observation>
</entry>
```

3.3 Negating Clinical Statements

Usually, clinical statements in a CDA document assert positive statements. A procedure element represents a procedure that took place and an observation represents an observation about a resident condition or a lab result. In this IG, when `negationInd` is set to true, it is understood that it negates the act as described by the act's descriptive properties (including `act.code`, `procedure.effectiveTime`, `observation.value`, etc.) and any of the act's components, rather than at the level of a specific value in the act. The inert properties such as `act.id`, `act.moodCode`, and `act.confidentialityCode` are not negated and always have the same meaning. In other words, when an act is negated, it indicates that the event as specified did not occur. For example, if the clinical statement is asserting that a procedure was not performed on a certain date, the `negationInd` is set to true. This means the procedure was not performed on that date. For further details and examples, see the definition of `Act.negationInd` in the HL7 Reference Information Model (RIM), Version 2.07 (the version of the HL7 RIM from which CDA, Release 2 is derived) and the discussion of *Negation Indicators in RIM Classes in Core Principles and Properties of V3 Models*.

3.4 Summary Document serviceEvent Codes

For the summary report, the `documentationOf/serviceEvent/code` element records the type of summary data reported. This corresponds to the NHSN form type. This pattern is similar to that used in C-CDA (all releases) (e.g., Operative Note).

4 USING THIS IMPLEMENTATION GUIDE

This chapter describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA templates, the mechanism by which templates are bound to vocabulary, and additional information necessary to understand and correctly implement the normative content found in Volume 2 of this guide.

4.1 Levels of Constraint

The CDA standard describes conformance requirements in terms of three levels corresponding to three types of conformance statements:

- Level 1 requirements impose constraints upon the CDA Header. The body of a Level 1 document may be XML or an alternate allowed format. If XML, it must be CDA-conformant markup.
- Level 2 requirements specify constraints at the section level of a CDA XML document: most critically, the section code and the cardinality of the sections themselves, whether optional or required.
- Level 3 requirements specify constraints at the section and entry level within a section.

Note that these levels are rough indications of what a recipient can expect in terms of machine-processable coding and content reuse. They do not reflect the level or type of clinical content, and many additional levels of reusability could be defined.

4.2 Conformance Conventions Used in This Guide

4.2.1 Templates and Conformance Statements

Conformance statements within Volume 2 of this IG are presented as constraints from Trifolia Workbench, a template repository.⁵ An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:86-7345). The digits in the conformance number before the hyphen identify which IG the template belongs to and the number after the hyphen is unique to the owning IG. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential. Conformance numbers in this guide associated with a conformance statement that is carried forward from a previous version of this guide will carry the same conformance number from the previous version. This is true even if slightly edited. If a conformance statement is entirely new, it will have a new conformance number.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the identifier `oid` or identifier `urn`, and whether the template is [open or closed](#). The identifier `oid` is the `templateId/@root` value; all `templateIds` have an `@root` value. Newer and/or versioned templates also have an `@extension` value, which is a date identifying the version of this template; such templates are identified by `urn` and the HL7 version (`urn:h17ii`). The `urn`

⁵ Lantana Consulting Group, Trifolia workbench. <https://trifolia.lantanagroup.com/>

identifier includes both the @root and @extension value for the templateId (for example, identifier urn:hl7ii:2.16.840.1.113883.10.20.5.5.41:2014-06-09).

Each section and entry template in Volume 2 of this guide includes a context table. The "Contained By" column indicates which templates use this template, and if the template is optional or required in the containing template. The "Contains" column indicates any templates that the template uses.

Figure 11: Context Table Example

XXX: Allergy Problem Act (V2) Contexts

Contained By:	Contains:
Allergies Section (entries optional) (V2) (optional)	Allergy - Intolerance Observation (V2)
Allergies Section (entries required) (V2) (required)	Author Participation

Each template also includes a constraint overview table to summarize the constraints in the template.

Figure 12: Constraints Overview Table Example

XPath	Card.	Verb	Data Type	CONF#	Fixed Value
observation[identifier: oid:2.16.840.1.113883.10.20.22.4.31]					
@classCode	1..1	SHALL		XXXX	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		XXXX	2.16.840.1.113883.5.1001 (ActMood) = EVN
code	1..1	SHALL		XXXX	
@code	1..1	SHALL		XXXX	2.16.840.1.113883.6.96 (SNOMED CT) = 445518008
value	1..1	SHALL	PQ	XXXX	
@unit	1..1	SHALL	CS	XXXX	2.16.840.1.113883.11.20.9.21 (AgePQ_UCUM)
templateId	1..1	SHALL		XXXX	
@root	1..1	SHALL		XXXX	2.16.840.1.113883.10.20.22.4.31
statusCode	1..1	SHALL		XXXX	
@code	1..1	SHALL		XXXX	2.16.840.1.113883.5.14 (ActStatus) = completed

The following figure shows a typical template's set of constraints presented in Volume 2 of this guide. The next chapters describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors. The expression “such that it” means, you (**SHALL/SHOULD/MAY**) have one of those things that look like that, but you can also have another one of those things that look different. The example below states that you must have templateId with a root of 2.16.840.1.113883.10.20.22.4.31 but you can also have other template identifiers (IDs).

Figure 13: Constraints Format Example

Age Observation

[observation: identifier oid:2.16.840.1.113883.10.20.22.4.31 (open)]

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:XXXX).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF: XXXX).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:XXXX) such that it
 - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.31" (CONF: XXXX).
4. **SHALL** contain exactly one [1..1] **code** (CONF:7615).
 - a. This code **SHALL** contain exactly one [1..1] **@code**="445518008" Age At Onset (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96 **STATIC**) (CONF: XXXX).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF: XXXX).
 - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF: XXXX).
6. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="PQ" (CONF:XXXX).
 - a. This value **SHALL** contain exactly one [1..1] **@unit**, which **SHALL** be selected from ValueSet [AgePQ UCUM](#) 2.16.840.1.113883.11.20.9.21 **DYNAMIC** (CONF: XXXX).

4.2.2 Template Versioning

A new version of an existing IG reuses templates from the previous version. During the ballot phase or update phase, templates carry the designation “Published as part of <name of IG>” to indicate the template is unchanged from the previous version or “Draft as part of <name of IG>” to indicate a new or revised template.

If there are no substantive changes to a template that has been successfully published, the template will carry the same **templateId/@root** (identifier oid) and **templateId/@extension** as in the previous IG (in the case of older templates, the **@extension** attribute will not be present). During a new ballot or update phase, “Published as part of <name of IG>” is appended to the main heading for the template to indicate that the template cannot be commented on in the ballot or update.

A revised version of a previously published template keeps the same **templateId/@root** as the previous version, but it is assigned a new **templateId/@extension**. The notation “(Vn)” (V2, V3, etc.) is also added to the template name. Versions are not necessarily forward or backward compatible. A versioning may be due to substantive changes in the template and/or the fact that a contained template has changed. The “(Vn)” designation is persistent; it appears with that template when it is used in subsequent guides. During a new ballot or update phase, “Draft as part of <name of IG>” is appended to the main heading for the template

to indicate that it may be voted on in the ballot or commented on in the update; this “Draft as part of <name of IG>” designation is updated to “Published as part of <name of IG>” in final publication versions.

A revised version of a template is explicitly linked to the prior version. When a new version appears for the first time in an IG, a detailed change log is automatically generated.

4.2.3 Open and Closed Templates

HAI LTCF templates are, with one exception, closed templates. This means that the template constraints specify everything that is allowed. In open templates, by contrast, all of the features of the CDA R2 base standard are allowed except as constrained by the templates.

The exception to closed templates in HAI reports is that the `structuredBody` is open: it may contain sections not specified in this guide. The content of such unspecified sections is not processed by NHSN.

4.2.4 Conformance Verbs (Keywords)

The keywords **SHALL**, **SHOULD**, **MAY**, **NEED NOT**, **SHOULD NOT**, and **SHALL NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.⁶

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

The keyword “**SHALL**” allows the use of `nullFlavor` unless the requirement is on an attribute or the use of `nullFlavor` is explicitly precluded.

4.2.5 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format “m..n” where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more
- 1..n at least one and not more than n

⁶ HL7 Version 3 Publishing Facilitator's Guide. <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 14: Constraints Format—only one allowed

- | |
|---|
| <ol style="list-style-type: none">1. SHALL contain exactly one [1..1] participant (CONF:2777).<ol style="list-style-type: none">a. This participant SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230). |
|---|

In the next figure, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint.

Figure 15: Constraints Format—only one like this allowed

- | |
|--|
| <ol style="list-style-type: none">1. SHALL contain exactly one [1..1] participant (CONF:2777) such that it<ol style="list-style-type: none">a. SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230). |
|--|

4.2.6 Optional and Required with Cardinality

The terms *optional* and *required* describe the *lower* bound of cardinality as follows:

Optional means that the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*] or similar. In these cases, the element may not be present in the instance.

Required means that the number of allowable occurrences of an element must be at least 1; the cardinality will be expressed as [m..n] where m >=1 and n >=m for example [1..1] or [1..*]. In these cases, the element must be present in the instance. If an element is required but is not known (and would otherwise be omitted if it were optional), it must be represented by a null flavor. See “[Unknown and No Known Information](#)”.

4.2.7 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC and SNOMED CT vocabularies.

Note that value-set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC**) do not appear in CDA submissions; they tie the conformance requirements of an IG to the appropriate code system for validation.

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL**, **SHOULD**, **MAY**, etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. Value-set constraints can be **STATIC**, meaning that they are bound to a specified version of a value set, or **DYNAMIC**, meaning that they are bound to

the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

Figure 16: Binding to a Single Code

2. **SHALL** contain exactly one [1..1] **code** (CONF:15403).
- a) This code **SHALL** contain exactly one [1..1] **@code**="11450-4" Problem List (CONF:15408).
 - b) This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF: 31141).

The notation conveys the actual code (11450-4), the code's `displayName` (Problem List), the OID of the `codeSystem` from which the code is drawn (2.16.840.1.113883.6.1), and the `codeSystemName` (LOINC).

HL7 Data Types Release 1 requires the `codeSystem` attribute unless the underlying data type is "Coded Simple" or "CS", in which case it is prohibited. The `displayName` and the `codeSystemName` are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 17: XML Expression of a Single-code Binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 V3 Normative Edition 2010*⁷ sections on Abstract Data Types and XML Data Types R1.

Value set tables are presented below the first template that uses that value set; links are provided in subsequent templates that use the same value set. The value set tables include the value set identifier, a description, a link (where appropriate), and a list of codes in the value set. Ellipses in the last row of value-set members shown indicate that the list is an excerpt and the complete source must be accessed to see all members. Where the table is an excerpt and no link is provided, the full set of values are contained in the `hai_voc.xls` spreadsheet included with this package.

⁷ HL7 Version 3 Interoperability Standards. [http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010](http://www.hl7.org/memonly/downloads/v3edition.cfm-V32010)

Figure 18: Example Value Set Table

Value Set: Referral Types 2.16.840.1.113883.11.20.9.56 A value set of SNOMED CT codes descending from "3457005" resident referral (procedure). Value Set Source: https://vsac.nlm.nih.gov			
Code	Code System	Code System OID	Print Name
44383000	SNOMED CT	2.16.840.1.113883.6.96	Resident referral for consultation
391034007	SNOMED CT	2.16.840.1.113883.6.96	Refer for falls assessment (procedure)
86395003	SNOMED CT	2.16.840.1.113883.6.96	Resident referral for family planning (procedure)
306106002	SNOMED CT	2.16.840.1.113883.6.96	Referral to intensive care service (procedure)
306140002	SNOMED CT	2.16.840.1.113883.6.96	Referral to clinical oncology service (procedure)
396150002	SNOMED CT	2.16.840.1.113883.6.96	Referral for substance abuse (procedure)
...			

4.2.8 Data Types

All data types used in a CDA document are described in the CDA R2 normative standard. All attributes of a data type are allowed unless explicitly prohibited by this standard.

4.2.9 Succession Management

CDA-conformant HAI instances use the elements defined in the CDA header (`documentId`, `setId`, `version number`, and `relatedDocument/typeCode`) to manage replacements and updates of the documents. As with all CDA documents, the `ClinicalDocument/id` uniquely identifies a document instance (an electronic file). Incremented version numbers identify subsequent versions of the document.

NHSN assigns each participating facility a root OID. The vendor system generates the `ClinicalDocument/setId`. The vendor is responsible for extending its OID as necessary to support the several unique numbering schemes it must generate; these include document identifiers and facility-generated procedure identifiers.

4.3 XML Conventions Used in This Guide

4.3.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation⁸ in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document

⁸ W3C, *XML Path Language*. <http://www.w3.org/TR/xpath/>

instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

XPath statements appear in this document in a monospace font.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and catenated with a '/' symbol.

Figure 19: XML Document Example

```
<author>
  <assignedAuthor>
    ...
    <code codeSystem='2.16.840.1.113883.6.96'
          codeSystemName='SNOMED CT'
          code='17561000'
          displayName='Cardiologist' />
    ...
  </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the `code` could be selected with the XPath expression in the next figure.

Figure 20: XPath Expression Example

```
author/assignedAuthor/code/@code
```

4.3.2 XML Examples and Sample Documents

XML examples appear in figures in this document in this monospace font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure 21: ClinicalDocument Example

```
<ClinicalDocument xmlns="urn:h17-org:v3">
  ...
</ClinicalDocument>
```

Within the narrative, XML element (`code`, `assignedAuthor`, etc.) and attribute (`SNOMED CT`, `17561000`, etc.) names also appear in this monospace font.

This package includes sample documents as listed in the [Contents of the Package](#) table.

4.4 Supporting Tools

4.4.1 Validation

This guide expresses CDA R2 constraints and provides a non-normative set of Schematron schemas based on a technology-neutral formalism, which can test template conformance.

Schematron is “a language for making assertions about patterns found in XML documents.” The schemas provided for CDA and for this package support two-stage validation. First, the CDA schema CDA.xsd validates the basic structural and semantic requirements of any CDA instance. Second, the IG-specific Schematron schema validates the specific requirements of this package.

Validation services are provided through the NHSN import mechanism and by Lantana Group’s CDA Validator (<https://www.lantanagroup.com/validator/>). The CDA Validator is an online application that validates a CDA document’s conformance to several standards and IGs; it includes the Schematron files described above.

4.4.2 Generation of Narrative Block

Clinical documents generated by clinicians for a resident chart can assume an almost infinite set of semantic structures. For this reason, CDA relies on a narrative block (section/text) to convey the comprehensive clinical report, i.e., all the information that a human reader would consider the definitive, legal content of the record. (Human readability and rendering requirements are described in CDA R2, Section 1.2.3. See [References](#).)

In contrast, the structure and semantics of HAI reports to the NHSN are tightly constrained for unambiguous insertion into the NHSN database. Few elements allow unstructured, uncoded narrative. The definitive, human-readable, legal contents of a report can be derived entirely from the CDA titles and coded entries. Therefore, for the convenience of implementers, this project created a transform that derives the narrative block from the CDA entries. Use of this transform is not required; implementers can use local methods to create the CDA narrative block.

4.4.3 Display Transforms

The content required for correct interpretation by a human reader of a compliant instance must be displayable using any CDA stylesheet. Thus, instances conforming to this IG can be viewed using CDA.xsl or any other stylesheet.

In addition, this project has a customized stylesheet that conforms more closely to the display format typical of such records.

5 REFERENCES

- CDA Validator, <http://www.lantanagroup.com/validator>.
- *HL7 Clinical Document Architecture, Release 2 (CDA R2), Normative Edition*. (May 2005). http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
- *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, R1.1 (US Realm)*. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
- *HL7 Version 3 Interoperability Standards*, Normative Edition 2010. <http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010>
- *HL7 Version 3 Publishing Facilitator's Guide*, Release 1. (2005). <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm> (Login required)
- *HL7 Version 3 Standard: Refinement, Constraint and Localization to Version 3 Messages, Release 2* (9/9/2015). <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm> (Login required)
- *HL7 Vocabulary Domains*. http://vico.org/CDAR22005_HL7SP/infrastructure/vocabulary/NullFlavor.htm
- Lantana Consulting Group, Trifolia workbench. <https://trifolia.lantanagroup.com/>
- LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute. Available at: <http://loinc.org>
- NHSN website, <http://www.cdc.gov/nhsn/>.
- SNOMED CT®: SNOMED Clinical Terms SNOMED International Organization. Available at: <http://www.ihtsdo.org/snomed-ct>.
- W3C, *XML Path Language (XPath) Version 1.0* (November 16, 1999, revised September 7, 2015). <http://www.w3.org/TR/xpath/>

APPENDIX A — ACRONYMS AND ABBREVIATIONS

AMA	American Medical Association
AR	Antimicrobial Resistance
ARO	Antimicrobial Resistance Option
AUR	Antimicrobial Use and Resistance Module
C-CDA	Consolidated CDA
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CDI	<i>C. difficile</i> infection
CLABSI	Central Line Associated Blood Stream Infection
CPT	Current Procedural Terminology
EHR	electronic health record
FHIR	Fast Healthcare Interoperability Resources
FOIA	Freedom of Information Act
HAI	Healthcare Associated Infection
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
ICP	infection control professional
ICU	intensive care unit
ID	identifier
IG	implementation guide
IHTSDO	International Health Terminology Standard Development Organisation
IV	intravenous
LabID	laboratory-identified
LOINC	Logical Observation Identifiers Names and Codes
LTCF	Long Term Care Facility
MDRO	Multidrug-resistant organism
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NHSN	National Healthcare Safety Network
NICU	Neonatal Intensive Care Unit
NUCC	National Uniform Claim Committee
OID	object identifier
OPC	Outpatient Procedure Component
POM	Process and Outcome Measure
R1.1, R2	Release 1.1, Release 2, etc.
RIM	Reference Information Model
SCA	Specialty Care Area
SDS	Synthetic Data Set
SME	subject matter expert
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
STU	Standard for Trial Use
UCUM	Unified Code for Units of Measure
URL	Uniform Resource Locator
URN	Universal Resource Name
VAE	Ventilator Associated Event
VAT	Vascular Access Type
XML	Extensible Markup Language
XPath	XML Path Language

APPENDIX B — HIGH-LEVEL CHANGES FROM PREVIOUS RELEASES

This appendix summarizes the main changes to the standard. This IG is the third STU release on the path to Normative release 1..

3rd HL7 Standard for Trial Use (STU)

Two reports were revised:

- HAI Single-Person Report Generic Constraints LTCF (V4)
 - Removed and prohibited patient/administrativeGenderCode
- Laboratory Identified MDRO or CDI Event Report for LTCF (V4)

One section was updated:

- NHSN Social History Section (V4) (from NHSN Healthcare Associated Infection Reports)

One template was added:

- Sex (from NHSN Healthcare Associated Infection Reports)

Two templates were removed:

- Gender Identity (C-CDA)
- Birth Sex (C-CDA)

2nd HL7 Standard for Trial Use (STU)

Two reports were revised:

- HAI Single-Person Report Generic Constraints LTCF (V4)
 - Added patient/languageCommunication to represent the patient's preferred language
- Laboratory Identified MDRO or CDI Event Report for LTCF (V4)

One section was updated:

- NHSN Social History Section (V3) (from NHSN Healthcare Associated Infection Reports)

Two templates were added:

- Interpreter Needed Observation (from NHSN Healthcare Associated Infection Reports)
- Interpreter Used by Patient This Encounter Observation (from NHSN Healthcare Associated Infection Reports)

2nd Update to 1st HL7 Standard for Trial Use (STU)

Two reports were revised:

- HAI Single-Person Report Generic Constraints LTCF (V3)

- Laboratory Identified MDRO or CDI Event Report for LTCF (V3)

One section was added:

- NHSN Social History Section (V2) (from NHSN Healthcare Associated Infection Reports)

Two templates were added:

- Birth Sex Observation (C-CDA)
- Gender Identity Observation (V4) (C-CDA)

1st Update to 1st HL7 Standard for Trial Use (STU)

Two reports were revised:

- HAI Single-Person Report Generic Constraints LTCF (V2)
- Laboratory Identified MDRO or CDI Event Report for LTCF (V2)

Three templates were revised:

- LTCF Monthly Summary Data for MDRO, CDI, UTI, and Prevention Process Measures (V2)
- Summary Data Observation LTCF (V2)
- Summary Encounter LTCF (V2)

One value set was revised:

- NHSNReportNoEventsMDROLTCF

Two value sets were added:

- Codes for Denominators for Long Term Care Locations LTCF
- Codes for Prevention Process Measures LTCF

APPENDIX C — DOCUMENT AND SECTION CODES (NON-NORMATIVE)

The templates in Volumes 2 use LOINC codes to identify the document type and section types. The document and section templates specify which code to use. This appendix is provided as a convenient summary for the implementer.

Table 3: Document and Section Codes

codeSystem	Name	code	Meaning
2.16.840.1.113883.6.1	LOINC	51897-7	Healthcare Associated Infection Report
		09252-8	Report No Events Section
		18769-0	Findings Section
		51900-9	Summary Data Section
		46240-8	History of Encounters

APPENDIX D — CONSOLIDATED CDA (C-CDA) TEMPLATES REFERENCED IN THIS GUIDE

A few NHSN templates conform to templates in the C-CDA guide: *HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, R1.1 (US Realm)*.⁹

Table 4: C-CDA Template OIDs

Template Title	Template OID
Encounter Activities	2.16.840.1.113883.10.20.22.4.49
Result Observation	2.16.840.1.113883.10.20.22.4.2

⁹ HL7, *Consolidated CDA*. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

APPENDIX E — EXAMPLE INSTANCE IDENTIFIERS (NON-NORMATIVE)

As discussed in [Background](#) and [Example Instance Identifiers](#), much of the development of this guide was driven by a pilot project in July 2007. The pilot project assigned example OIDs to a fictional facility and vendor to illustrate the numbering schemes for which facilities and vendors are responsible. In practice, these identifiers will be assigned by facilities and software applications within those facilities participating in the NHSN.

All example OIDs in this IG and in the accompanying sample files begin with 2.16.840.1.113883.3.117.1.1.5. and are documented below for reference.

Each OID-owner such as a facility or vendor controls the structure of the OIDs it assigns under its root and is responsible for ensuring that each identifier it issues is globally unique. A vendor must, for example, ensure that there is no duplication amongst the `setIds` issued by its various software installations. The example instance identifiers in this guide use the following plan for assigning instance identifiers:

Table 5: Structure of Example OIDs

Usage	OID
a healthcare facility OID	2.16.840.1.113883.3.117.1.1.5.1.1
its resident IDs	2.16.840.1.113883.3.117.1.1.5.1.1.1
its personnel IDs	2.16.840.1.113883.3.117.1.1.5.1.1.2
a vendor OID	2.16.840.1.113883.3.117.1.1.5.2.1
its first software installation	2.16.840.1.113883.3.117.1.1.5.2.1.1
its <code>setIds</code>	2.16.840.1.113883.3.117.1.1.5.2.1.1.1
its document IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.2
its encounter IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.3
its procedure IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.4
its event / incident IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.5
etc.	

Conformant to that structure, the following example instance identifiers may be used in this guide and in the sample files.

Table 6: Values of Example Instance Identifiers Used in This Guide

Facility IDs and Facility-assigned OIDs		
Usage	OID	extension
a location in a facility	2.16.840.1.113883.3.117.1.1.5.1.1	9W
a resident ID	2.16.840.1.113883.3.117.1.1.5.1.1.1	123456
facility personnel:		
author ID	2.16.840.1.113883.3.117.1.1.5.1.1.2	anAuthorID
legal authenticator ID	2.16.840.1.113883.3.117.1.1.5.1.1.2	aLegalAuthenticatorID
performer (nurse)	2.16.840.1.113883.3.117.1.1.5.1.1.2	24242424
Vendor-software-assigned OIDs		
Usage	OID	extension
software ID	2.16.840.1.113883.3.117.1.1.5.2.1.1	aSoftwareID
setId	2.16.840.1.113883.3.117.1.1.5.2.1.1.1	31
document ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.2	20202201 93
encounter ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.3	31
procedure ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.4	92
event / incident ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.5	21987654321 11987654321

APPENDIX F — VOCABULARY HEURISTICS FOR CODES AND VALUE SETS (NON-NORMATIVE)

The CDC has identified questions and allowable responses for HAI form fields. In many cases these questions and responses have been mapped to local CDC/NHSN codes, and it is the CDC's intention to identify corresponding standard codes. Within the CDC, different groups have done vocabulary mapping work (e.g., with HL7 V2 messages), often with different results, and efforts are underway to not only reconcile internal CDC vocabulary usage, but also reconcile CDC vocabulary usage with the Healthcare Information Standards Technology Panel (HITSP) recommendations.

Vocabularies recommended in this guide are primarily standard vocabularies recommended for use in particular domains. In many cases these vocabularies are further constrained into value sets for use within this guide or were previously constrained into value sets by the CDC.

The incremental strategy for vocabulary reconciliation for codes, code systems, and value sets in this document is as follows.

Code and codeSystem Selection

- Where there is conflicting precedent within the CDC, CDC will advise on the preferred CDC code system.
- Where there is a preferred code system within the CDC that is consistent with HITSP recommendations, existing CDC-cited code systems are used.
- Where there is a preferred code system within the CDC that is not consistent with HITSP recommendations, divergence from HITSP is flagged, and reconciliation between CDC and HITSP is planned (but outside the scope of this document).
- Where there is no established precedent within the CDC, available HITSP recommendations will be followed.
- Where there is no established precedent within the CDC and no HITSP recommendations, precedent in prior CDA IGs will be followed.
- Where there is no established precedent within the CDC, no HITSP recommendations, and no prior CDA IG precedent:
 - An attempt will be made to map CDC/NHSN local codes to standard codes (e.g., SNOMED, HL7 V3 vocabularies).
 - Where there is no corresponding standard code, the CDC/NHSN local code will be cited. (Submitting local CDC/NHSN codes to SNOMED is outside the scope of this document.)
- If post-coordination of SNOMED terms and codes would be required to capture the CDC/NHSN concept, the local CDC/NHSN code will be used.

Value Set Assignment and Maintenance

- Where there is conflicting precedent within the CDC, CDC will advise on the preferred CDC value set.

- Where there is a preferred CDC value set that is consistent with HITSP recommendations, existing CDC value sets are used.
- Where there is a preferred CDC value set that is not consistent with HITSP recommendations, divergence from HITSP is flagged, and reconciliation between CDC and HITSP is planned (but outside the scope of this document).
- Where there is no established precedent within the CDC, available HITSP recommendations will be followed.
- Where there is no established precedent within the CDC and no HITSP recommendations, then precedent in prior CDA IGs will be followed.
- Where there is no established precedent within the CDC, no HITSP recommendations, and no prior CDA IG precedent, new value sets will be created, each having a value set OID assigned by the CDC.