CDAR2_IG_PHCR_R2_RR_D1_2017MAY
Vol1_Introductory_Material

HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1 - US Realm

May 2017

Volume 1 – Introductory Material

HL7 Standard for Trial Use (STU) Ballot

Sponsored by:
Public Health and Emergency Response Group
Structured Documents Work Group

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/apply-cpt-license-license-requirements
SNOMED CT	International Healthcare Terminology Standards Development Organization (IHTSDO) http://www.ihtsdo.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 222.nucc.org. AMA licensing contact: 312-464-5022 (AMA IP services)

Structure of This Guide

Four volumes comprise this *HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 – US Realm.* 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 HL7 Clinical Document Architecture, Release 2 (CDA R2) templates for this guide along with lists of all templates, code systems, value sets, and changes from the previous version. Volumes 3 and 4 provide informative guidance for the creators and the receivers/users of the Reportability Response.

Acknowledgements

This guide was produced and developed through a collaborative effort of the Centers for Disease Control and Prevention (CDC), the Council of State and Territorial Epidemiologists (CSTE), the Association of Public Health Laboratories (APHL), public health surveillance practitioners, Electronic Health Record vendors, and the HL7 Public Health and Emergency Response (PHER) Work Group for a Reportability Response. A list of data elements for the Reportability Response was developed by a collaborative effort that spanned the CDC, CSTE, APHL, and the PHER Work Group. CDC provided some funding to our partner organizations to support these activities. The project team members that participated in the development of this implementation guide are:

- Laura Conn, Director, Health Information Strategy Activity, CSELS, CDC
- Erin Holt Coyne, Director, Surveillance Systems and Informatics, Tennessee Department of Health, and Co-chair, HL7 PHER Work Group
- Sarah Gaunt, Senior Information Analyst, Lantana Consulting Group
- Marc Hadley, Senior Principal Software Systems Engineer, The MITRE Corporation
- John W. Loonsk, Executive Sponsor of the Public Health Case Reporting Project, PHER WG, Chief Medical Informatics Officer, CGI Federal, and consultant to APHL
- Pace Ricciardelli, Healthcare Software Systems Engineer, The MITRE Corporation
- John Roberts, Director of Interoperability and Standards, Tennessee Department of Health
- Dawn Sievert, Chief Scientist, Lantana Consulting Group
- Wendy L. Wise, Senior Project Manager, Lantana Consulting Group

Note to Ballot Readers—Specific Feedback Areas

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

We would like to get specific feedback and advice on the following:

- Non-normative (informative) guidance documentation:
    - Currently this information is contained in Volume 3 (for senders of a Reportability Response CDA document) and Volume 4 (for receivers of a Reportability Response CDA document)
    - It is expected that this informative content will be published on GForge in a similar manner to the Support Files (e.g., non-normative Schematron files) with a link on the HL7 page stating that the material is available for download:

Note to Ballot Readers - Links for Next Step Healthcare Reporting and Management

This note will be removed in the published version of the IG.

Internet links for next-step reportable condition reporting and management are an important part of bidirectional communication needs with healthcare. In a Reportability Response, the links will be provided by a limited set of trusted sources and will be secured under technologies protecting sensitive health information, but there are presentation challenges.

In this guide, these links are fully expressed (e.g. http://health.authoritywest.gov/epi/diseases/zika) because some older EHRs will require copying them out of the Reportability Response and pasting them into a web browser. Most EHRs will be able to hyperlink the fully expressed link, but nevertheless these links will be long and unwieldy (the tables are present to help manage them).

Please comment on the feasabilty of including text hyperlinks (e.g. rendered as "Zika Supplemental Reporting") in next step modeling.

Note to Ballot Readers – Reportability Response Priority

This note will be removed in the published version of the IG.

By law, some reportable conditions require very urgent (e.g. within 4 hours) action by healthcare personnel. In this guide, the Reportabilty Response includes a **Reportability Response Priority** data element that can be used by EHRs to implement urgency-sensative healthcare workflows.

Please comment on the feasabilty of Public Health Agencies assigning all next-step actions a priority of either: “Action required,” “Action recommended,” or “Information only.” Will all three choices be used? Are other choices needed?

Note to Ballot Readers—Temporary Codes

This note will be removed in the published version of the IG.

There are several temporary codes in this IG. All temporary codes start with "TEMP_CODE_". Codes to replace these temporary codes have been requested and will be included in the final publication version of the IG.

Note to Ballot Readers—Items for Voting

This note will be removed in the published version of the IG.

This ballot contains four volumes.

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 Reportability Response” below the template name. **These MAY be voted on.**

EXAMPLE:

3.1 Determination of Reportability

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.19:2017-04-01 (open)]

Draft as part of Reportability Response

- Templates that have been brought in unchanged from another balloted and published implementation guide are signified by the wording “Published as part of <name of IG>” below the template name. **These MAY be commented on.** The committee SHALL determine that the disposition is “Not related”; and, if appropriate, the committee MAY refer the comment to the work group responsible for the content in question or direct the commenter to lodge an STU comment.

EXAMPLE:

3.7 External Document Reference

```
[externalDocument: identifier
urn:hl7ii:2.16.840.1.113883.10.20.22.4.115:2014-06-09 (open)]

Published as part of Consolidated CDA Templates for Clinical Notes (US Realm)
DSTU R2
```

Volume 3 and Volume 4:

- The content in Volumes 3 and 4 **MAY** be commented on but is not considered part of the normative content in this IG.

Contents

1 INTRODUCTION

1.1 Purpose

The purpose of this *HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 – US Realm* is to specify a standard for a Reportability Response document in the Clinical Document Architecture, Release 2 (CDA R2) US Realm format. Each Reportabilty Response document will be a companion to an electronic Initial Case Report (eICR) document such as specified in the *HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, STU Release 1.1 – the Electronic Initial Case Report (eICR) – US Realm January 2017*[1].

The submission of public health case reports for reportable (infectious and non-infectious) conditions is required by law in all States and Territories in the United States. Case reports are important for tracking high-level disease trends at the Local, State and Federal levels, but they also feed surveillance and outbreak management systems that support the investigation and management of individual cases and outbreaks in routine and emergent public health situations. State, Local and Territorial Public Health Agencies (PHAs) are authorized to receive identifiable case data to enable these activities.

In addition to supporting critical public health functions in State, Local, and Territorial Public Health Agencies (PHAs), the data from case reports indirectly support notifications between PHAs and the Centers for Disease Control and Prevention (CDC) for the Nationally Notifiable Disease Surveillance System (NNDSS) and nationwide disease monitoring.

Electronic case reporting (eCR) from Electronic Health Records (EHRs) involves both the automated initiation of case reports and the delivery of existing electronic EHR data to public health[2]. Together, these eCR advances can significantly lower healthcare provider reporting burden while signficantly advancing case reporting outcomes. Automated electronic case reporting from EHRs is important to public health surveillance for several reasons. It can help PHAs get timely clinical care data. It can address the chronic under-reporting of clinical cases. It can better support the management of cases in public health outbreaks and emergencies. It can support legally required case reporting of suspect condtions. It can complement electronic laboratory reporting by providing clinical and demographic data that are not included in laboratory reports. And it can support reporting for conditions in which a laboratory result is not a definitive criterion.

The Reportabilty Response

The automated reporting of information from healthcare to public health can bring many benefits, but it also brings new capabiltes and needs for information to flow from public heath to clincial care. For some time clinical care providers have expressed the

[1] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=436

[2] For the purposes of the implementation guide, the term “public health” refers to Public Health Agencies, their delegates, and their intermediaries. “Public Health Agency” refers to a specific governmental public health organization.

concern that they do not receive the information they want from public health for all of the information they provide to public health. This “bi-directional communications” problem relates to perceptions of the quantity of data that flows in one direction, but also to the limited specificity, patient context, and workflow integration of the information that is offered to clinical care from PHA web sites and other sources. Among other things, healthcare providers have expressed the desire to have information on the status of reportable conditions in their jurisdictions with succinct next steps they should be taking relative to these conditons and their patients. These are some of the purposes of the Reportability Response document.

There are other needs for the Reportabilty Response in eCR. Healthcare organizations will need to use this information on reportable conditions in multiple clinical roles and workflows, and at differing levels of public health urgency:

- There are times when a provider, such as the clinician of record, needs information regarding legally mandated reporting requirements and important public health conditions.
- Frequently, clinical support staff or Infection Control Practitioners (ICPs) are responsible for following-up on reportable conditions and insuring that all reporting is accomplished.
- EHR systems administrators need confirmation that eICRs have been properly shared with public health and if errors or reporting problems occur that they are rapidly resolved.

The intent is to have one Reportability Response shared with clinical care for each eICR that is received. The sharing of the Reportability Response with clinical care will serve several functions including to:

- Communicate the reportability of condition(s) in eICR
- Indicate what PHA(s) has been sent a report
- Identify necessary clinical follow-up activities including any additional reporting needs
- Provide clinical support information for identified reportable conditions
- Provide appropriate contact information for the primary responsible PHA
- Confirm eICR receipt and processing

Some PHA’s have indicated that they also want copies of Reportability Responses (when they have not generated them) to monitor and track the reporting process and to understand what information has been conveyed to clinical care organizations.

1.2 Audience

This implementation guide provides public health systems developers the specifications for implementing functionality used by public health to generate a Reportability Response. This IG also provides EHR vendors and clinical implementers with the specifications for receiving and processing Reportability Responses. The implementation guide will be instructive to healthcare providers, public health staff, analysts, and health information exchange organizations among others. Users of this implementation guide must be familiar with the details of the HL7 CDA R2 document

construction and the *Consolidated CDA Templates for Clinical Notes, DSTU 2.1* (C-CDA R2.1) templates. Additionally, users will benefit from knowledge of the *HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, STU Release 1.1 – the Electronic Initial Case Report (eICR) – US Realm January 2017*.

1.3 Organization of this Guide

This implementation guide is organized into four volumes. Volume 1 contains primarily narrative text describing this Implementation Guide, whereas Volume 2 contains normative CDA R2 template definitions. Volumes 3 and 4 contain informative guidance for the sender and receiver of the Reportability Response.

1.3.1 Volume 1: Introductory Material

This document, Volume 1, provides an overview of Clinical Document Architecture, Release 2 (CDA R2), summaries of recent changes to the standard, and information on how to understand and use the CDA R2 templates provided in Volume 2.

Chapter 1—Introduction

Chapter 2—Use Case for eCR and the Reportability Response. This section describes the use case for eCR and the Reportability Response, along with the overall flow, assumptions, conditions, actors, roles, and scenarios.

Chapter 3—CDA R2 Background. This section contains select background material on the CDA R2 base standard to aid the reader in conceptualizing the "templated CDA" approach to implementation guide development.

Chapter 4—Using This Implementation Guide. This section describes the rules and formalisms used to constrain the CDA R2 standard. It describes the formal representation of CDA R2 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—Reportability Response Conformance Guidance. This section describes conformance guidance that is specific to this implementation guide.

Chapter 6—Reportability Response Data Requirements. This section describes identified data requirements for the Reportability Response and how they map to the CDA R2 base standard.

Appendices— The Appendices include a list of acronyms and abbreviations and a summary of extensions to CDA R2.

1.3.2 Volume 2: CDA R2 Templates and Supporting Material

Volume 2 includes CDA R2 templates and prescribes their use for a set of specific document types. The main chapters are:

Chapter 1—Document-Level Templates. This chapter defines the Reportability Response document type and its specific header constraints, and references the required and optional section-level template containments.

Chapter 2—Section-Level Templates. This chapter defines the section-level templates referenced within the document and references the required and optional entry-level template containments.

Chapter 3—Entry-Level Templates. This chapter defines entry-level templates, called 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.

Chapter 4—Participation and Other Templates. This chapter defines templates for CDA R2 participants (e.g., author, performer) and other fielded items (e.g., address, name) that cannot stand on their own without being nested in another template.

Chapter 5—Template Ids in This Guide

Chapter 6—Value Sets in This Guide

Chapter 7—Code Systems in This Guide

1.3.3 Volume 3: Sender Guidance

This volume contains informative guidance on generating the narrative sections of a Reportability Response CDA document.

1.3.4 Volume 4: Receiver Guidance

This volume contains informative guidance on the rendering and visualization of a Reportability Response CDA document and of possible notification, alerting, routing, and queuing implementations in healthcare.

1.4 Background

State, Local and Territorial laws and regulations require the reporting of cases, and some suspect cases, of specific infectious and non-infectious conditions to Public Health Agencies. This case reporting supports condition monitoring, surveillance and response management. While case reporting from clinical care to PHAs is considered a core public health function, its electronic implementation has been slow to advance nationally because of a number of challenges. Laws requiring the reporting of infectious and non-infectious conditions are written individually by jurisdictions. Geographic differences in condition prevalence and other jurisdictional variations have created a complex array of reporting expectations making it difficult for providers to know when, where, and how to report.

Clinical care providers, for their part, have been historically inconsistent in reporting from clinical care by any process. For example, a CDC study indicated that of the cases of Lyme disease recorded as a clinical diagnosis, only about one out of ten is reported to the appropriate Public Health Agency.[3]

Previous efforts to develop standards for the exchange of case data between healthcare and public health have been hampered by inter-organizational exchange issues and

[3] http://www.cdc.gov/media/releases/2013/p0819-lyme-disease.html

the problems they present for standards-based solutions. Some previous solution efforts have included trying to develop individual implementation guides for each individual condition (there are over 200 conditons that are reportable in most jurisdictions) and harmonizing all condition data and jurisdictional reporting differences into a single, consolidated data specification.

A goal of the eICR and of this Reportabilty Response standard is to define a singular standard that can be used for all conditions and in all jurisdictions in interorganizatonal exchange with EHRs and healthcare. Stage 3 of the CMS EHR Incentive Program (Meaningful Use) has identified electronic public health case reporting as a menu option for clinical reporters. This implementation guide also has a goal to contribute to certification criteria for consistent bi-directional exchange of information can occur between clinical care and public health. The Reportability Response is intended to be used in a one-to-one fashion with eICRs to complete the bi-directional exchange loop, support clinical care information needs, and initiate other activities such as the reporting of supplemental case data.

The benefits of having all-condition, all-jurisdiction eICR and Reportability Response specifications come with additional requirements. These include the need to capture supplemental data, when needed, from clinical care and the patient. This implementation guide provides a path to capture supplemental data from clinical care when it is needed for a condition or required by jurisdiction specific reporting requirements through identifying reportable conditions for a specific patient in clinical care and providing the opportunity for providers and reporters to link to supplemental data reporting.

Several public health jurisdictions may be involved in the reporting process. The Local and/or State PHA in which the patient resides may require by law a case report for a specific condition. At times, a different Local or State PHA where care was provided may also require a report. Some Local PHAs may not be able to receive eICRs and/or have not provided jurisdiction-specific electronic reporting rules. Some of these PHAs will want cases to be received by another PHA on their behalf. An example of this is when a State PHAs receives and processes cases in their integrated surveillance system from where a Local PHA can then view them. The Reportability Response needs to be able to record and convey information about all of these involved PHA's in order to handle the different permutations and identify to clinical care the appropriate PHA for contact and follow-up.

This Reportability Response implementation guide builds on experience, specifications and lessons learned from the previous releases of the HL7 Implementation Guide for CDA Release 2: Public Health Case Report; the Council of State and Territorial Epidemiologists (CSTE) "Minimum EHR Data for an Electronic Initial Case Report (eICR)"; work done by CSTE and CDC on the Reportable Conditions Knowledge Management System (RCKMS); and CSTE's work on the Reportable Conditions Trigger Codes.

1.5 Scope of the Implementation Guide

The following areas are in scope for this implementation guide:

- The data elements to be shared by public health in a Reportability Response
- The full specification of a Reportability Response

- The structure of the Reportability Response in HL7 CDA R2 format
- A description of the stakeholders and actors
- The definition of a standard document format including structure and content (i.e., vocabulary)
- Identification of requirements for clinical care and EHR vendors to receive a Reportability Response and support its use, when appropriate, by *Providers*, *Reporters*, and *EHR System Administrators*

The following areas are out of scope for this implementation guide:

- The specific methods for public health to share or transmit Reportability Response CDA documents with healthcare and PHAs
- The specific internal EHR workflows for *Providers*, *Reporters*, and *EHR System Administrators* to receive and process Reportability Response CDA documents (Informative guidance and critical data for these workflows are provided in Volume 4 of this implementation guide)
- The definition of specifications and guidelines on reportable event criteria (e.g., defining reportable conditions). This implementation guide does not define the reporting criteria or the potential data elements that a jurisdiction may want in a complete report
- The description of the process for PHAs to perform follow-up activities, including case management and national notification
- The definition of specifications and guidelines for reporting by means other than the transmission of an electronic message or document (e.g., telephone voice, manual web-entry and mailed or faxed information)
- The identification of security requirements, methodologies, procedures, and/or protocols
- The identification of information and data stewardship practices and policies

1.6 Current Project

This *HL7 CDA® R2 Implementation Guide: Reportability Response , Release 1, STU Release 1.0 – US Realm* specification was developed and produced by the HL7 Public Health and Emergency Response Workgroup and co-sponsored by the HL7 Structured Documents Workgroup. It is intended to be used in conjunction with the *HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, STU Release 1.1 – the Electronic Initial Case Report (eICR) - US Realm January 2017 or subsequent releases.*

The project currently allows for inclusion of the following general information in a Reportability Response CDA document:

- A reference to the eICR that triggered the generation of the Reportability Response and when that eICR was received by a public health system
- A human-readable version of summary narrative text regarding reportability, reporting, and next steps for *Providers* and *Reporters* in clinical care
- A human readable short description of the Reportability Response to be used as a work queue or in-box subject header inside of EHRs

- The relative urgency of action by the healthcare provider or their designee
- Contact information for the patient and provider in question
- Contact information for the responsible public health jurisdiction(s)

Since public health case reports may contain information about multiple reportable conditions and each condition is potentially reportable in multiple jurisdictions, the Reportability Response will also contain data and meta-data organized by the combination of condition and jurisdiction for processing, routing, queuing, rendering, and managing inside of EHRs including:

- Coded representation of the public health jurisdiction(s) and condition(s)
- The determination of reportability provided by a public health decision support system
- If additional data are needed to fully determine reportability
- Human readable descriptions of next step reporting, care, and reference information
- Appropriate links and descriptions to access next step actions and information
- Condition specific next step guideline and treatment information
- Indication as to whether further action is required on the part of the provider
- Additional specimen collection information

The Reportability Response will contain sensitive personally identifiable information and personal health information. Like the eICR, it will need to be shared and stored according to appropriate security and privacy practices. The Reportability Response will be generated by trusted PHAs and their representatives. The protections necessary for protecting sensitive patient data will also protect reporting and resource links to ensure that they only connect to specific, trusted partners.

Comments regarding errata or enhancements may be noted on the HL7 STU Comments page: http://www.hl7.org/dstucomments/.

1.7 Stakeholders

Table 1: The key stakeholder groups interested in Reportability Response Use Case

Stakeholders	Description
Clinical Care Provider	Any supplier of a healthcare service, i.e., a person or organization that furnishes, bills, or is paid for clinical care in the normal course of business. Includes physicians and clinical care provider staff, as well as ancillary clinical care personnel (e.g., laboratory personnel).
Electronic Health Record (EHR) / Electronic Medical Record (EMR)	The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. Source: http://www.himss.org/ASP/topics_ehr.asp. For purposes of this implementation guide, EHR can also be interpreted to refer to applications that some vendors may call an Electronic Medical Record (EMR).
Health IT Vendor	A vendor or supplier is a company/consortium that provides health information technology products and/or services, in this case, for supporting health or healthcare.
Intermediary	An organization that is in the information flow between a healthcare organization and a Public Health Agency regarding case reporting. Examples: • A Health Information Exchange (HIE) organization, a clinical trust and exchange network, and a shared infrastructure and routing platform like that of APHL AIMS
Laboratory	The producer of laboratory test results (filler or, at times, placer of a laboratory order).

Stakeholders	Description
Laboratory Information System (LIS)	An application to streamline the management of laboratory processes including data collection, workflow management, and report generation. May provide an automatic interface to laboratory analytical instruments to transfer verified results to nurse stations, chart carts, and remote physician offices. Also referred to as a Laboratory Information Management System.
Public Health Agency (PHA)	A governmental entity at the federal, state, territorial, local or tribal level that is legally entitled to establish public health case reporting requirements and receive case reports.
Public Health Decision Support (PHDS)	A service that provides clinical care personnel with knowledge about reporting cases to public health and information about the condition that has been identified. Examples include the Reportable Conditions Knowledge Management System (RCKMS), the Notifiable Condition Detector (NCD), and Electronic Support for Public Health (ESP).
Public Health Information System	Jurisdictional information systems that may, among other things, receive public health case reports.
Standards Development Organization	An organization that identifies the need for, locates interested parties, and writes specifications that all parties in a particular field of human endeavor can use to their mutual benefit. For the purpose of this document, the field is health or health interoperability and recognition by the American National Standards Institute (ANSI) or the International Standards Organization (ISO) is accepted as evidence that an organization is a SDO.

1.8 Future Work and Relationships to Other Projects/Standards

Related work has developed and published the *HL7 CDA® R2 Implementation Guide: Public Health Case Report, Release 2, STU Release 1.1 – the Electronic Initial Case Report (eICR) - US Realm January 2017* – a standard for an initial electronic case report that can be used for all conditions and in all jurisdictions. This Reportability Response implementation guide specifies the document to pair with each eICR for the purposes of providing information back to clinical care organizations (and, at times, PHAs when they did not directly create it).

Future work on eCR standards may inlcude:

- Developing HL7 FHIR versions of both of the eICR and Reportability Response CDA document standards
- Developing FHIR representations of common supplemental case questions and data that can be used by programs and jurisdictions to complement, when needed, data in the eICR
- Specifying and advancing form standards such as through IHE RFD / HL7 Structured Data Capture to record data supplemental data

- Harmonizing eICR and supplemental data with national notification data to ensure that adequate standards and minimal burden exist for the exchange of case report data between PHA and Federal agencies
- Standardizing, where appropriate, and update Reportable Condition Trigger Codes and reportable condition decision logic to advance the sensitivity and specificity of reporting from clinical settings and the comparability of reported data
- Identifying and advancing electronic methods for getting needed case report data directly from patients
- Harmonizing data standards used for other public health purposes to minimize demands on clinical care providers and EHR system vendors
- Advancing additional standards, as needed, to support public health investigations of outbreaks and events

1.9 Contents of the Package

Table 2: Contents of the Package

Filename	Description	Standards Applicability: Normative	Standards Applicability: Informative
CDAR2_IG_PHCR_R2_RR_D1_2017MAY _Vol1_Introductory_Material.docx	Implementation Guide Introductory Material	Chapter 1 Chapter 4 Chapter 5 Chapter 6 Appendix A Appendix B	Chapter 2 Chapter 3
CDAR2_IG_PHCR_R2_RR_D1_2017MAY _Vol2_Templates_and_Supporting_Material.docx	Implementation Guide Template Library and Supporting Material	Templates Appendixes	Examples
CDAR2_IG_PHCR_R2_RR_D1_2017MAY _Vol3_Sender_Guidance.docx	Informative sender guidance for generating narrative	n/a	Guidance file
CDAR2_IG_PHCR_R2_RR_D1_2017MAY _Vol4_Receiver_Guidance.docx	Informative receiver guidance for visualization of narrative	n/a	Guidance file
CDAR2_IG_PHCR_R2_RR_D1_2017MAY_ Sample.xml	Reportability Response CDA XML sample file	n/a	Sample file

Filename	Description	Standards Applicability: Normative	Standards Applicability: Informative
CDAR2_IG_PHCR_R2_RR_D1_2017MAY _ Sample.html	HTML Rendering of sample file using sample stylesheet	n/a	HTML rendering of sample file
CDAR2_IG_PHCASERPT_RR_PT_STYLESHEET.xsl	Sample stylesheet for rendering	n/a	Stylesheet
GForge link: CDA Schema	CDA Schema	n/a	CDA Schema
CDAR2_IG_PHCR_R2_RR_D1_2017MAY_SCHEMATRON.sch CDAR2_IG_PHCR_R2_RR_D1_2017MAY_VOC.xml	Schematron files	n/a	Schematron Vocabulary

2 USE CASE FOR eCR AND THE REPORTABILITY RESPONSE

The scope of this implementation guide is limited to the generation of a Reportability Response from public health and their representatives and Reportability Response use within clinical care organizations and PHAs. However, the Reportability Response is only one part of the overall eCR flow. The broader eCR flow is depicted in the Context Use Case diagrams (Figures 1 and 2) below, and is also referenced in the Use Case Assumptions as well as the Pre-Conditions and Post-Conditions sections of this chapter. The broader eCR picture is included both to show how the Reportability Response fits as a response to the eICR and to highlight important components that should be addressed in future work to provide full eCR implementation. The Reportability Response Use Case diagram and the Receiver guidance in Volume 4, show additional detail for use of the Reportability Response inside a clinical care organization.

2.1 Context Use Case Flow Diagrams

The diagrams below show the context for the overall flow of eCR, including where creation of the Reportability Response fits within the flow. The Context Use Case flow diagrams shows (Figure 1) the eICR could be:

- Manually initiated by a provider
- Automatically initiated based on a match of patient data to one or more codes in a set of codes provided by public health
- Created and sent from an EHR system
- Created in an EHR and sent through a designee of clinical care, such as an HIE or trust network

as shown on the left side of Figure 1.

Likewise, the eICR could be:

- Received directly by the PHA
- Received by an intermediary for the PHA, such as the APHL AIMS platform or an HIE

as shown on the right side of Figure 1.

Confirm Reportability is a function that operates against the eICR once received by the PHA (or its intermediary). Its role is to determine if the report fully meets jurisdictional reporting requirements and to which jurisdiction(s) the report should be sent. Again, in keeping with the general depiction of the eCR flow, the confirmation of reportability could be met by:

- A centralized but jurisdiction-specific decision support service such as RCKMS

- A localized decision support service such as ESP
- Manual inspection at a jurisdiction in the absence of an automated approach

Figure 1: Context Use Case—Electronic Case Reporting to a Public Health Agency

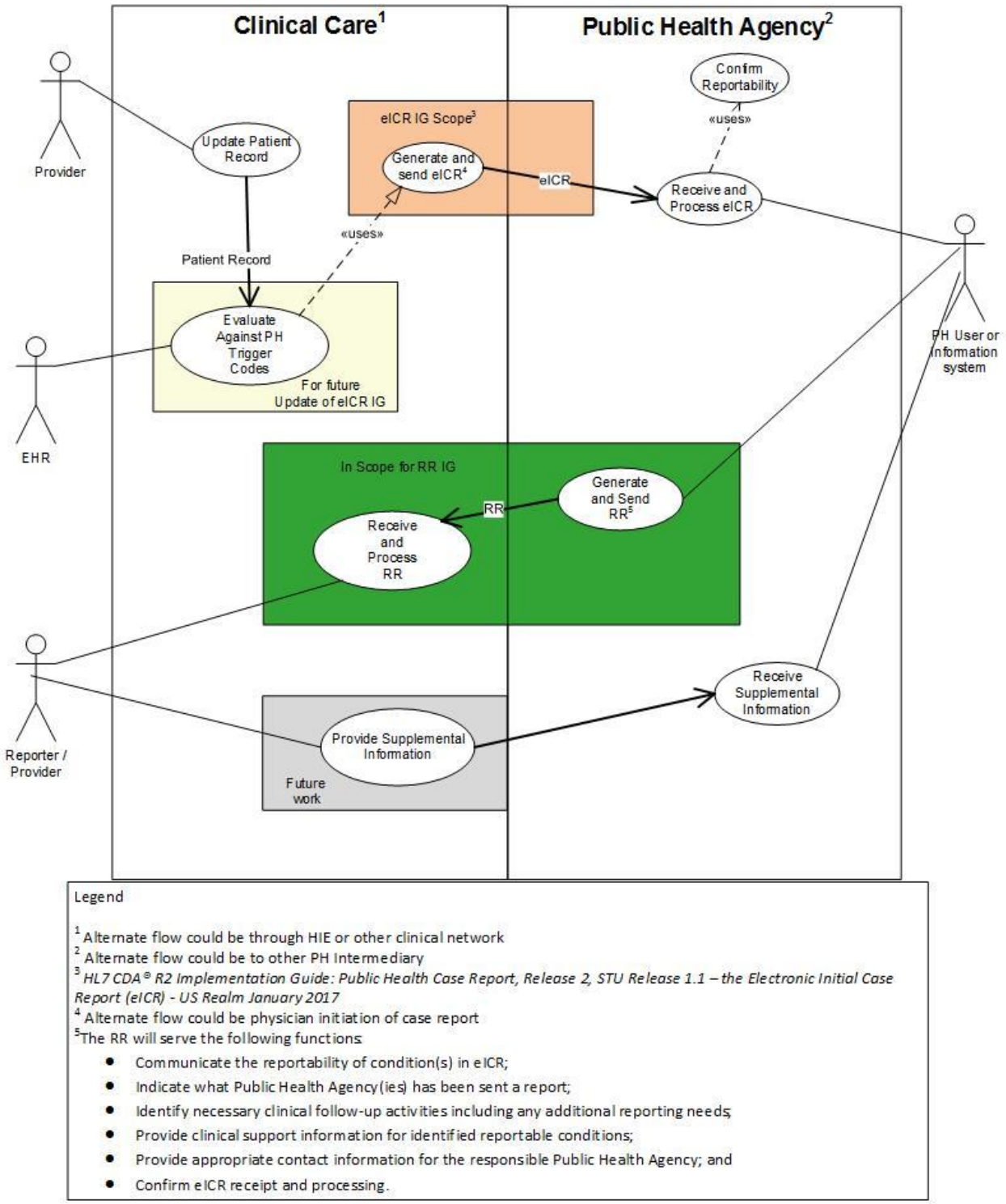
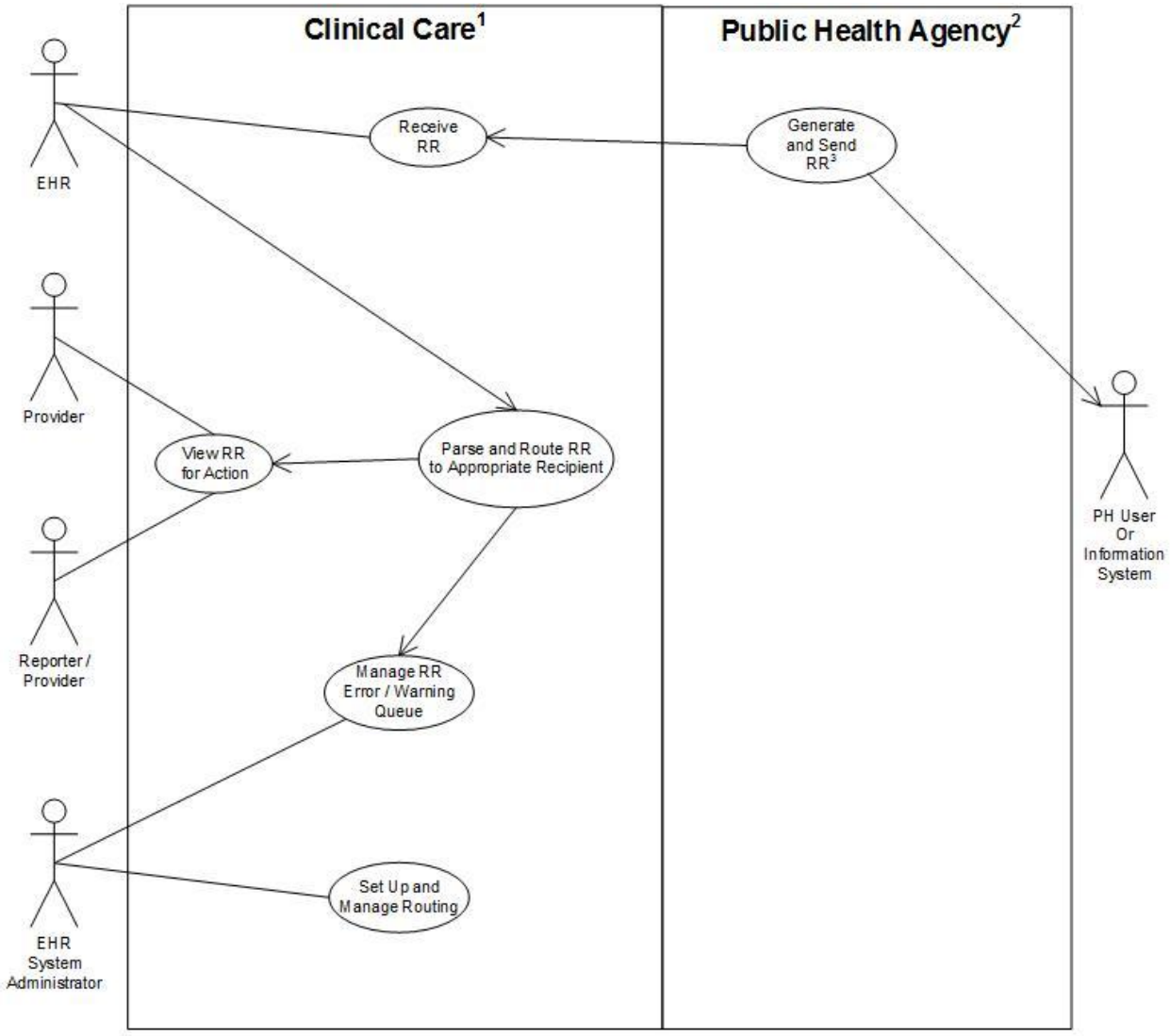


Figure 2: Context Use Case—Use of a Reportability Response (RR) by Clinical Care



Legend

[1] Alternate flow could be through HIE or other clinical network
[2] Alternate flow could be to other PH Intermediary
[3] The RR will serve the following functions:

- Communicate the reportability of condition(s) in eICR;
- Indicate what Public Health Agency(ies) has been sent a report;
- Identify necessary clinical follow-up activities including any additional reporting needs;
- Provide clinical support information for identified reportable conditions;
- Provide appropriate contact information for the responsible Public Health Agency; and
- Confirm eICR receipt and processing.

2.2 Use Case Assumptions

These items are assumed to be in place to support the eCR use case.

- Patient-level clinical information is entered, imported, or accessed by a healthcare provider using an EHR system.
- Broadly-acceptable security and transport protocols, patient identification methodology, privacy and security procedures, coding, vocabulary, and normalization standards exist and are in use by the EHR system and PHA system.
- The EHR system contains or has access to all relevant information and data (e.g., demographic, clinical, laboratory, pharmacy) to generate a complete and accurate eICR.
- Appropriate data and information stewardship practices are adopted by exchange partners.
- Network and policy infrastructure exist to enable consistent, appropriate, and accurate information exchange across exchange partners.
- The PHA system may be a single stand-alone system or a component-based architecture. The PHA may interface with other systems that are used to help create, populate, or transmit the Reportability Response to clinical care.
- The PHA system is in place, is capable of generating a Reportability Response, and sends the report in a standardized structured format in accordance with requirements described in this implementation guide.
- The PHA system is capable of sending the Reportability Response to an EHR system or its intermediary system.
- Intermediary systems (e.g., HIEs, trust networks, a shared public health platform), if used, are responsible for passing transport-level acknowledgements for each "hop" between the EHR system and the public health information system.
- These transport level-acknowledgments may not pass through multiple hops and as such may not be considered an authoritative acknowledgement. There is an assumption that this guide will provide both higher-level acknowledgment of successful eICR processing and reliable round trip processing.

2.3 Pre-Conditions

The following must be in place:

- An authoritative set of reportable condition trigger codes, as provided and defined by public health (RCTC - available at PHIN VADS), is maintained and used within the EHR system.
- The creation of an eICR is initiated by one of two methods:
    - An automated match of information in a patient record for an encounter to a set of trigger codes within the EHR
    - Manual initiation of the creation of an electronic report to public health by a provider

- The EHR system populates/generates a report using all appropriate information (e.g., data elements and terminology) for the eICR.
- The receiving system receives and processes the eICR.
- The PHA system and/or its intermediary system has received the eICR.
- eICRs are ultimately grouped and de-duplicated by receiving system(s).
- A record of an eICR sent from the EHR to the PHA is stored in a log within the authoring system at the EHR.
- A record of receipt of the eICR is recorded in a log in the PHA system and/or its intermediary system.
- A public health decision support system has processed the eICR using appropriate jurisdictional reporting rules.
- A narrative summary and short subject description of the reportability status has been created.
- Descriptive text and appropriate links for additional reporting needs and reportable condition guidance have been identified.

2.4 Post-Conditions

- The EHR system or its intermediary system has received the Reportability Response.
- Reportability Responses have been managed, grouped, and routed by the receiving EHR system.
- EHR system renders the Reportability Response for clinical users when needed.
- EHR system can access and present the eICR associated with the Reportability Response to the clinical user when requested.
- A record of a Reportability Response sent from public health to the clinical care provider is stored in a log at the PHA and/or its intermediary.
- The Reportability Response has been shared, as appropriate, with the involved PHAs.
- A record of receipt of the Reportability Response is recorded in a log in the EHR system.

2.5 Actors and Roles

Table 3: The actors and a description of their roles are included in the table below

Actor	Role
Provider	• Update information in the EHR System
EHR System (clinical care provider system)	• Collect, receive, and/or store data on a patient record • Consume and maintain trigger codes • Match trigger code and generate eICR • Create report and transport to intermediary system or appropriate PHA • Receive, route, and render the Reportability Response from the PHA system • Make eICR available with associated Reportability Response when requested • Maintain a work queue (e.g., inbox) for Reportability Responses to be delivered for action
EHR System Administrator	• Set-up and manage the routing of the Reportability Response to the appropriate recipient • Manage and act on documents in the error/warning queue
Reporter	• Responsible for submission of case reports from a clinical care organization to PHAs (At times, the provider is also the reporter.)
Public Health Agency Information System	• Receive eICR from EHR system or intermediary • Determine reportability status using predefined jurisdiction- and condition-specific rules • Generate the Reportability Response • Send the Reportability Response to the EHR system or its intermediary
Public Health Jurisdiction User	• Use the information contained in the PHA system
Clinical Care or Clinical Care and Designee (e.g., HIEs)	• Implement and use EHR System; or • As designee of clinical care (e.g., HIEs): ○ Receive eICR from EHR system and send to Intermediary or PHA system
Public Health Agency (or PHA and Intermediary)	• Receive eICR from EHR system or clinical care designee • Confirm reportability • Send eICR and Reportability Response (when requested) to PHA system (if PHA intermediary)

2.6 Reportability Response Scenarios

The Reportability Response supports a number of functions in clinical care and public health. It will play a key role in communicating information in circumstances that can include several different roles in clinical care, multiple reportable conditions, trust networks and health information exchanges, public health intermediaries, and multiple PHAs. Listed below are a number of common Reportability Response scenarios. They do not represent all of the possible scenarios or permutations thereof.

2.6.1 One or More Reportable Condition in One or More Jurisdiction

In the most common scenario, the Reportability Response will communicate that one or more conditions are reportable, provide information about what clinical next step activities may need to occur, and other relevant resources.

In this case, a clinical care provider enters information into an EHR about a patient that matches one or more of the Reportable Condition Trigger Codes (RCTC), the EHR generates an eICR, the eICR is securely shared with public health (or its intermediary), and a public health decision support system uses the appropriate set of rules to confirm reportability.

The eICR and, at times, the Reportability Response are shared with the appropriate PHA(s) (if they are not already there), and the Reportability Response is shared with the originating clinical care organization. Inside of the clinical care organization, the Reportability Response is put into a work queue (or secure e-mail inbox) to notify the provider of the condition(s) and the status of legally required reporting. In unusual circumstances, the provider may want to be alerted. Frequently, the Reportability Response will either be directly routed to a clinical care staff "reporter's" work queue, or will be sent there by the provider, for notification and follow-up. EHR system administrators will also be able to ensure that there have been no issues with the reporting process.

2.6.2 Undetermined Reportability

There are circumstances where all data that are needed to determine reportability are not available from an eICR.

In this case, a clinical care provider or supporting system enters information into an EHR about a patient that matches one or more of the Reportable Condition Trigger Codes (RCTC) trigger codes, the EHR generates an eICR, the eICR is securely shared with public health (or its intermediary), and a public health decision support system uses the appropriate set of rules, but reportability cannot be confirmed for the relevant jurisdiction(s) because necessary data are not available.

The related eICR is deleted and the Reportability Response may, or may not, be shared with the appropriate PHA(s) based on preferences (and if they are not originating it). A Reportability Response is shared with the involved clinical care organization to "close the loop" on the eICR that had been shared and providers and/or reporters are notified that one or more reportable conditions may be present depending on the information in unavailable data. The provider or reporter may then manually initiate an eICR with an explanation that includes the missing data. Manually initiated eICRs, representing significant *Provider / Reporter* suspicion of a reportable condition, are always shared with the relevant PHA(s).

2.6.3 No Reportable Conditions

Trigger codes are designed to specifically trigger an eICR for reportable conditions, but reporting rules can be complex and there are circumstances where something that is thought to be reportable may not meet all reporting criteria for a given jurisdiction.

In this case, a clinical care provider enters information into an EHR about a patient that matches one or more of the Reportable Condition Trigger Codes (RCTC) trigger

codes, the EHR generates an eICR, the eICR is securely shared with public health (or its intermediary), and a public health decision support system uses the appropriate set of rules, but no reportability is determined for the relevant jurisdiction(s).

The related eICR is deleted and is not forwarded to a PHA (if it is not already there). The Reportability Response is shared with the involved clinical care organization to "close the loop" and for audit purposes on the eICR that had been shared, but neither providers nor reporters receive notification unless they specifically ask for it.

2.6.4 Reporting Issue

All eICRs are intended for machine processing on receipt including electronic decryption, content parsing and validation, decision support processing and, when necessary, sending, parsing and consumption by a separate public heath surveillance system. To be able to maintain the reporting process, to have comparable data at all of the different steps of this process, and to ensure that EHRs are using current Reportable Condition Trigger Code set versions and codes, it is important to be able to communicate reporting warnings and errors back to EHR system administrators.

In this case, a clinical care provider enters information into an EHR about a patient that matches one or more of the Reportable Condition Trigger Codes (RCTC) trigger codes, the EHR generates an eICR, the eICR is securely shared with public health (or its intermediary).

But on receipt, the eICR may be found to be corrupt, it may be unencryptable, the xml may be malformed or not processable, some required eICR data may not be found, an outdated version of the RCTC may have been used to trigger it, or an old trigger code may still be in place in the EHR. In these and other circumstances, a Reportability Response will be generated and, if possible, sent back. The Reportability Response will include information about the problem; the appropriate error - if the eICR was not able to be processed, the appropriate warning – if the eICR was able to be processed, and / or notice of the use of an outdated code set or code.

Reportability Responses with eICR processing errors (they were not processed) are shared with EHR system administrators and follow-up by reporters or providers using alternate reporting mechanisms may be necessary to complete legally required reporting requirements. Reportability Responses with warnings or notifications of outdated trigger code sets (the eICR was still processed) are managed by clinical care in accordance with determined routing and notification based on the determination of reportability and other supporting information as in 2.6.1 - 2.6.3 above.

3 CDA R2 BACKGROUND

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 R2, have the following characteristics:

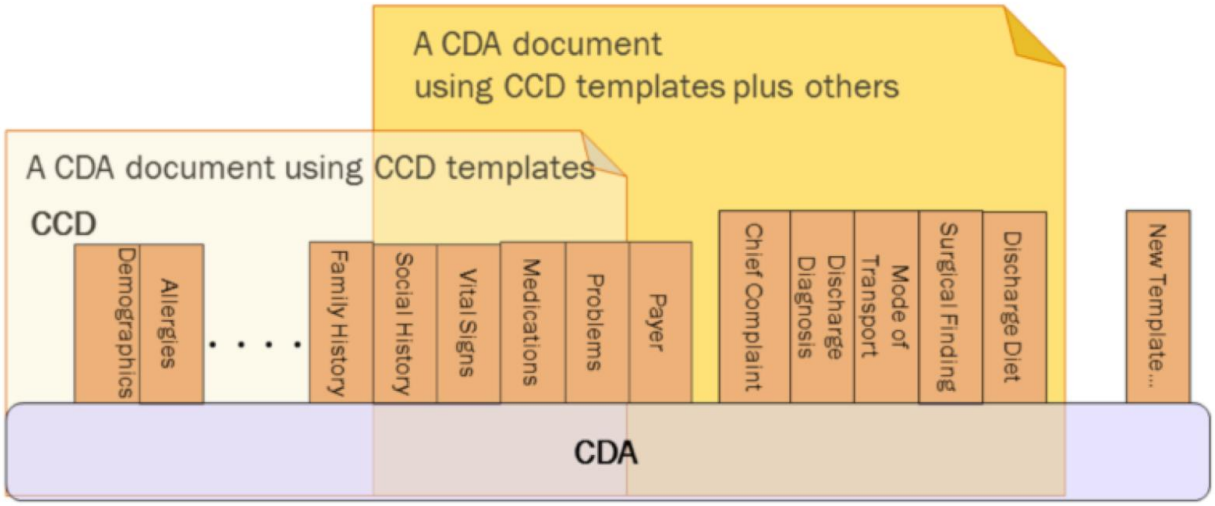
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA R2 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.

3.1 Templated CDA R2

CDA R2 can be constrained by mechanisms defined in the "Refinement and Localization" section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA R2 is referred to as a "CDA template." The "templated CDA" approach uses a library of modular CDA R2 template definitions. Templates can be reused across any number of CDA R2 document types, as shown in the following figure. Each template meets a defined purpose. Templates are managed over time through versioning. A template version is a specific set of conformance constraints designed to meet the template's purpose.

Figure 3: Templated CDA



There are many kinds of templates that might be created. Among them, the most common are:

Document-level templates: These templates constrain fields in the CDA R2 header, and define containment relationships to CDA R2 sections. For example, a History and Physical document-level template might require that the patient's name be present, and that the document contain a Physical Exam section.

Section-level templates: These templates constrain fields in the CDA R2 section, and define containment relationships to CDA R2 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 contains a Systolic Blood Pressure observation.

Entry-level templates: These templates constrain the CDA R2 clinical statement model in accordance with real-world observations and acts. For example, a Systolic Blood Pressure entry-level template defines how the CDA R2 Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.

Other templates: Templates that exist to establish a set of constraints that are reused in the CDA R2 document. These other templates are only used within another template, rather than on their own as a complete clinical statement. For example, US Realm Date and Time (DTM.US.FIELDED) includes a set of common constraints for recording time. This template is referenced several times with other templates used in the implementation guide. They reduce the need to repeat constraints in templates that use the common set.

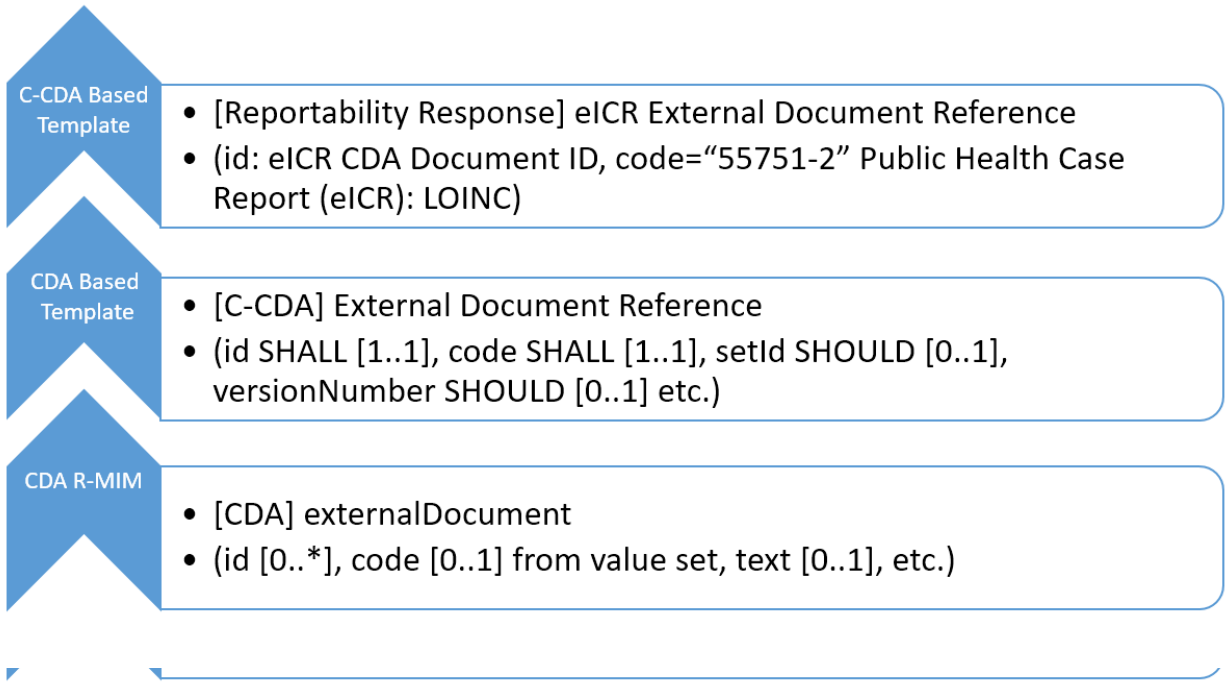
A CDA R2 implementation guide (such as this one) includes references to those template versions that are applicable. A CDA R2 instance populates the template identifier (templateId) field where it wants to assert conformance to a given template version. On the receiving side, the recipient can then test the instance for conformance against the CDA R2 Extensible Markup Language (XML) schema and also test the instance for conformance against asserted templates.

3.2 Further Constraining Existing Templates

A CDA template is a set of conformance constraints on either the base CDA model (CDA Refined Reference Information Model or R-MIM) or another CDA template (such as an existing C-CDA R2.1 templates). A new template is created that contains all the constraints of the base template and which further constrains that template. Constraints can only be tightened, not loosened. These further constraints can, for example, tighten a SHOULD to a SHALL or change [0..*] to [1..1]. Constraints can also be applied to vocabulary, for example binding to a specific code system or value set or only allowing the use of a single code (single value binding).

The following figure illustrates this "layering" of constraints starting from the most general (CDA R-MIM) at the bottom to the most specific (C-CDA Based Template) at the top. Each level conforms to the constraints of the level below it and adds a further set of conformance constraints to satisfy a particular use case:

Figure 4: Layering Constraints



The new template is fully conformant to the template it is based on, and contains the templateId of that template, as well as its own templateId. The following figure is an example of the presence of two templateIds to indicate that this template is asserting conformance to both templates.

Figure 5: Asserting Conformance to Two Templates

```
<externalDocument classCode="DOCCLIN" moodCode="EVN">
    <!-- [C-CDA R2.0 External Document Reference] -->
    <templateId root="2.16.840.1.113883.10.20.22.4.115" extension="2014-06-09" />
    <!-- [RR R1S1 eICR External Document Reference] -->
    <templateId root="2.16.840.1.113883.10.20.15.2.3.10" extension="2017-04-01" />
    ...
</externalDocument>
```

3.3 Status of a Template Version

Each version of a template has a status. For example, a template version can be draft, active, or deprecated, etc. The *HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1, October 2014, DSTU*[4] describes the various status states that may apply to a template version over the course of its lifecycle. Each version of a template has an associated status. Thus, one version of a template may be deprecated, while a newer version of that template may be draft or active.

[4] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=377

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 R2 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 Conformance Conventions Used in This Guide

The following sections describe conformance conventions specific to this implementation guide.

4.1.1 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by a conformance number at or near the end of the constraint (e.g., CONF:86-7345). The set of digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the set of digits after the hyphen are unique to the owning implementation guide. Together, these two sets of digits uniquely identify each constraint. These conformance numbers 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 carry the same conformance number as the previous version. This is true even if the previous conformance statement has been edited. If a conformance statement is entirely new it has a new conformance number."

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the object identifier (OID) or uniform resource name (URN), and whether the template is open or closed. The identifier OID is the templateId/@root value; all templateIds have an @root value. 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:hl7ii). The URN 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).

Templates in Volume 2 of the guide include contexts tables with a "Contained By" column indicating which documents or sections use this template and a "Contains" column indicating any entries that the template uses. Templates also include constraints overview tables, which summarize the constraint statements following the table. Value set tables, where applicable, and brief XML example figures are included with most templates.

A typical template, as presented in this guide, is shown in the Constraints Format Example figure below. The next sections describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, and containment relationships.

Figure 6: Constraints Format Example

3.1 Determination of Reportability

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.19:2017-04-01 (open)]

Draft as part of Reportability Response

Table 34: Determination of Reportability Contexts

Contained By:	Contains:
Reportability Information Organizer (required)	Determination of Reportability Reason Determination of Reportability Rule

This template represents the determination of reportability.

Table 35: Determination of Reportability Constraints Overview

XPath	Card.	Verb	Data Type	CONF #	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.15.2.3.19:2017-04-01)					
@classCode	1..1	SHALL		3315-354	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		3315-355	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		3315-347	

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` Observation (CodeSystem: `HL7ActClass urn:oid:2.16.840.1.113883.5.6` **STATIC**) (CONF:3315-354).
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` Event (CodeSystem: `HL7ActMood urn:oid:2.16.840.1.113883.5.1001` **STATIC**) (CONF:3315-355).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:3315-347) such that it
   a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.15.2.3.19"`

CONF:3315-358).

Table 36: Determination of Reportability

Value Set: Determination of Reportability urn:oid:2.16.840.1.113883.10.20.15.2.5.3			
Code	**Code System**	**Code System OID**	**Print Name**
TEMP_CODE_MAYBE	PHIN VS (CDC Local Coding System)	urn:oid:2.16.840.1.114222.4.5.274	Maybe reportable

The expression “such that it” at the end of one conformance statement links that conformance statement to the following subordinate conformance statement to further constrain the first conformance statement. To understand the full effect of this conformance construct, the two conformances must be considered as a single compound requirement. The subordinate conformance statement functions as a

subordinate clause (like a "where" clause), which is being applied on the first conformance statement.

The following example shows a compound conformance statement made up of two conformance statements joined by a "such that it" clause. The effect of this syntax can be interpreted as a "where" clause. Thus...

1. **SHALL** contain exactly one [1..1] templateId (CONF:81-7899) such that it
    a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31" (CONF:81-10487).

...is understood as:

1. This template **SHALL** contain exactly one [1..1] templateId where it contains exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31".

This means that you must have a template id with @root="2.16.840.1.113883.10.20.22.4.31", but you can also have other template ids with different valued attributes.

The next chapters describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors (see also Reportabillity Response Conformance Guidance).

4.1.2 Template Versioning

A new version of an existing implementation guide 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 implementation guide (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.

4.1.3 Open and Closed Templates

In open templates, all the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included. There are no closed templates in this implementation guide.

Open templates allow HL7 implementers to develop additional structured content not constrained within this guide. HL7 encourages implementers to bring their use cases forward as candidate requirements to be formalized in a subsequent version of the standard to maximize the use of shared semantics.

4.1.4 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.*

- 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.

When conformance statements are nested (or have subordinate clauses) the conformance statements are to be read and interpreted in hierarchical order. These hierarchical clauses can be interpreted as "if then, else" clauses. Thus...

a. This structuredBody **SHOULD** contain zero or one [0..1] **component** (CONF:1098-29066) such that it
    i. **SHALL** contain exactly one [1..1] **Plan of Treatment Section ((V2))** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.10:2014-06-09) (CONF:1098-29067).

...is understood as:

a. It is recommended (**SHOULD**) that the structuredBody contains a component.
    i. **If** the component exists, **then** it must contain a Plan of Treatment Section ((V2)),
    ii. **else** the component does not exist, and the conformance statement about the Plan of Treatment Section ((V2)) should be skipped.

In the case where the higher level conformance statement is a **SHALL,** there is no conditional clause. Thus...

a. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:1098-29086) such that it

i. **SHALL** contain exactly one [1..1] **Problem Section (entries required) ((V2))** (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.2.5.1:2014-06-09) (CONF:1098-29087).

...means that the structuredBody is always required to have a component.

4.1.5 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

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 7: Constraints Format—Only One Allowed

```
1. SHALL contain exactly one [1..1] participant (CONF:2777).
     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 8: Constraints Format—Only One Like This Allowed

```
1. SHALL contain exactly one [1..1] participant (CONF:2777) such that it
     a.  SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem:
        2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).
```

4.1.6 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. Conformances formulated with MAY or SHOULD are both considered "optional" conformances.

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 >=1 for example `[1..1]` or `[1..*]`. In these cases, the element must be present in the instance. Conformance statements formulated with SHALL are required conformances. If an

element is required but is not known (and would otherwise be omitted if it were optional), the @nullFlavor attribute must be used. See Unknown and No Known Information.

4.1.7 Unknown and No Known Information

Here, we provide guidance on representing unknown information. Further details can be found in the HL7 V3 Data Types, Release One specification that accompanies the CDA R2 normative standard. **However, it should be noted that the focus of C-CDA R2.1 is on the unambiguous representation of known data, and that in general, the often subtle nuances of unknown information representation are less relevant to the recipient.**

Many elements in CDA R2 contain a "@nullFlavor" attribute, used to indicate an exceptional value. Some flavors of Null are used to indicate that the known information falls outside of value set binding constraints. Not all uses of the @nullFlavor attribute are associated with a case where information is unknown. Allowable values for populating the attribute give more details about the reason the information is unknown, as shown in the following example.

Figure 9: nullFlavor Example

```
<birthTime nullFlavor="UNK"/>
<!--Sender does not know the birthTime, but a proper value is applicable -->
```

Use null flavors for unknown, required, or optional attributes:

- 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 patient 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 patient 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).

The list above contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA R2 normative edition.

Any SHALL, SHOULD or MAY conformance statement may use nullFlavor, unless the nullFlavor is explicitly disallowed (e.g., through another conformance statement which

includes a SHALL conformance for a vocabulary binding to the @code attribute, or through an explicit SHALL NOT allow use of nullFlavor conformance).

Figure 10: 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 11: 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 12: Unknown Medication Example

```
1. SHALL contain exactly one [1..1] code

<entry>
  <text>patient 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 13: Unknown Medication Use of Anticoagulant Drug Example

```
<entry>
  <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
    <text>I do not know whether or not patient 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.)

Previously, CCD, IHE, and HITSP recommended using specific codes to assert no known content, for example 160244002 No known allergies or 160245001 No current problems or disability. Specific codes are still allowed; however, use of these codes is not recommended.

These next examples illustrate nuances of representing information in coded fields when information is a negative assertion, for example it is not the case that the patient has an allergy or it is not the case that a patient takes a medication. The phrases "no known allergies" or "no known medications" are typically associated with this type of negative assertion.

Figure 14: 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>
```


Figure 15: 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 16: Value Completely Unknown

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

Figure 17: 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>
```

4.1.8 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 *in most cases* value-set identifiers (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC)** used in the binding definitions of template conformance statements do not appear in the XML instance of a CDA R2 document. The definition of the template must be referenced to determine or validate the vocabulary conformance requirements of the template.

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both an indication of stability and of coding strength for the binding. Value set bindings can be static, meaning that they bind to a specified version of a value set, or dynamic, meaning that they bind to the most current version of the value set. If a **STATIC** binding is specified, a date **SHALL** be included to indicate the value set version. If a **DYNAMIC** binding is specified, the value set authority and link to the

base definition of the value set **SHALL** be included, if available, so implementers can access the current version of the value set. When a vocabulary binding binds to a single code, the stability of the binding is implicitly **STATIC**.

Figure 18: 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 19: 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* sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy between the HL7 R1 Data Types and this guide in the in the implementation of translation code versus the original code. The R1 data type requires the original code in the root. The convention agreed upon for this implementation guide specifies a code from the required value set be used in the element and other codes not included in the value set are to be represented in a translation for the element. This discrepancy is resolved in HL7 Data Types R2.

In the next example, the conformant code is SNOMED-CT code 206525008.

Figure 20: Translation Code Example

```
<code code='206525008'
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
   <translation code='NEC-1'
      displayName='necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.19'/>
</code>
```

Value set tables are present below a template, or are referenced if they occur elsewhere in the specification, when there are value set bindings in the template. The value set table provides the value set identifier, a description, and a link to the source of the value set when possible. Ellipses in the last row indicate the value set members shown are examples and the true source must be accessed to see all members.

If a value set binding has a DYNAMIC stability, implementers creating a CDA R2 document must go to the location in the Uniform Resource Locator (URL) to check for the most current version of the value set expansion.

Figure 21: Example Value Set Table (Language)

Value Set: Language 2.16.840.1.113883.1.11.11526
A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes.
Value Set Source: http://www.ietf.org/rfc/rfc4646.txt

Code	Code System	Code System OID	Print Name
aa	Language	2.16.840.1.113883.6.121	Afar
ab	Language	2.16.840.1.113883.6.121	Abkhazian
ace	Language	2.16.840.1.113883.6.121	Achinese
ach	Language	2.16.840.1.113883.6.121	Acoli
ada	Language	2.16.840.1.113883.6.121	Adangme
ady	Language	2.16.840.1.113883.6.121	Adyghe; Adygei
ae	Language	2.16.840.1.113883.6.121	Avestan
af	Language	2.16.840.1.113883.6.121	Afrikaans
…			

4.1.9 Containment Relationships

Containment constraints between a section and its entry are indirect in this guide, meaning that where a section asserts containment of an entry, that entry can either be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..*] **entry** (CONF:8647) such that it

a. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (templateId:2.16.840.1.113883.10.20.22.4.48) (CONF:8801).

...the Advance Directive Observation can be a direct child of the section (i.e., section/entry/AdvanceDirectiveObservation) or a further descendent of that section (i.e., section/entry/…/AdvanceDirectiveObservation). Either of these are conformant.

All other containment relationships are direct, for example:

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.21" (CONF:7928).

The templateId must be a direct child of the section (i.e., section/templateId).

4.1.10 Data Types

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

4.1.11 Document-Level Templates "Properties" Heading

In Volume 2 of this implementation guide, each document-level template has a "Properties" heading for ease of navigation. The Properties heading is an organizational construct, underneath which relevant CDA R2 act-relationships and roles are called out as headings in the document.

4.2 XML Conventions Used in This Guide

4.2.1 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XML Path Language (XPath) notation in conformance statements and elsewhere to identify the Extensible Markup Language (XML) elements and attributes within the CDA R2 document 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 concatenated with a '/' symbol.

Figure 22: 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 23: XPath Expression Example

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

4.2.2 XML Examples and Sample Documents

Extensible Mark-up Language (XML) examples appear in figures in this document in this `monospace font`. XML elements (code, assignedAuthor, etc.) and attribute names (SNOMED CT, 17561000, etc.) also appear 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 24: ClinicalDocument Example

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

This publication package includes complete XML sample documents as listed in the Contents of the Package table.

5 REPORTABILITY RESPONSE CONFORMANCE GUIDANCE

5.1 Template Types

The CDA R2 templates expressed in this specification are grouped according to type: Document, Section, Entry, and Participating and Other. Templates are arranged alphabetically within type. Each template is presented with a template title followed by template type and object identifier (OID), and a table of hyperlinked nested and encompassing templates.

Due to the specialized nature of the Reportability Response use case, the majority of templates in this guide are new to this guide. The Reportability Response document template establishes the document header for the Reportability Response document type. This header extends the C-CDA R2.1 US Realm Header (V3) document type to include additional administrative and demographic elements unique to the Reportability Response.

In a few cases, the templates used in this guide are a reuse or specialization (further constraints added to existing templates) of templates from the *HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1*[5] (C-CDA R2.1).

5.2 Structure of a Reportability Response CDA Document

The narrative structure of a Reportability Response CDA document can take two different forms, depending on the processing status of the eICR CDA document to which it is in response. These forms are as follows:

- If the eICR document was processed, then all three top-level sections (Reportability Response Subject Section, Reportability Response Summary Section and Electronic Initial Case Report Section) will have narrative text elements:
    - Reportablity Response Subject Section
        - Subject text
    - Electronic Initial Case Report Section
        - eICR Identifier
    - Reportabiltiy Response Summary Section
        - Summary text
        - Tables of links and their descriptions
- If the eICR document was not processed and has errors then only the Electronic Initial Case Report Section will have a narrative text element:

[5] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408

- Electronic Initial Case Report Section
  - eICR Identifier (if available)
  - eICR Processing Error Reason(s)

5.3 CDA Narrative Creation: Sender Responsibilities

The sender of a Reportability Response document is responsible for, among other things, creating succinct, human-readable Subject and Summary narratives that express reportability information, some of which is derived from coded information contained elsewhere in the Reportability Response. The **Reportability Response Subject** is intended to be used as a subject in a queue (similar to an email subject) and as such should be of an appropriately short length. The **Reportability Response Summary** should contain the reportability determination, the responsible PHA(s), and the PHA(s) that will be sent the eICR (when deemed reportable).

At a minimum, the Reportability Response Subject narrative should contain:

- An indication of a reportable condition or of no reportable conditions
- A brief sentence that identifies the Condition(s) and the Responsible Agency(ies)

At a minimum, the Reportability Response Summary narrative should contain:

- The reportability determination of conditions identified in the corresponding eICR
  - For each condition that was determined to be reportable to a given "responsible agency" (may be based on rules from a "authoring agency" surrogate):
    - The name of the condition
    - The name of the "responsible agency(ies)" in which the condition was determined to be reportable (contact information for the primary "responsible agency" will be one of the links in the table that follows the narrative summary)
    - Identification of the agency(ies) that have been sent the corresponding eICR (in regard to reporting requirements)
  - For each condition where other data are needed to make a determination of reportability:
    - The name of the possible condition
    - The name of the primary "responsible agency" for any follow-up (contact information for the primary responsible agency will be one of the links in the table that follows the narrative summary)
    - The data that are needed to determined reportability
    - A request to manually initiate a new eICR with the needed data expressed in the explanation of why it is being sent, or a request to complete the responsible jurisdiction's case report form.
  - For each condition that is determined to be not reportable in a jurisdiction:

        - The name of the condition
        - The name of the "responsible agency(ies)" in which the condition was determined to be not reportable (Contact information for the primary "responsible agency" will be one of the links in the table that follows the narrative summary.)
- If the eICR was manually initiated:
    - If reportable, the information as indicated above should be included; or
    - If not reportable, because all manually initiated eICRs will be sent to PHAs, an indication that the eICR has been sent to one or more "responsible agency(ies)" and the name of the agency(ies) (contact information for the primary "responsible agency" will be one of the links in the table that follows the narrative summary).

The text descriptions of the links and the links in the table should follow this narrative summary in the Reportability Response and are as important as the **Reportability Response Summary** narrative to be presented to *Providers* and *Rreporters*.

Further information about expected content and formatting of the Reportability Response Subject and Summary narrative can be found in Volume 3 - Sender Guidance. Volume 3 contains examples that can be used by implementers to construct these sections in such a way that it may be easily and immediately usable by clinical care *Providers* and *Reporters*.

5.4 CDA Narrative Rendering: Receiver Responsibilities

The receiver of a Reportability Response, at a minimum, **SHALL** be able to display the following elements contained in the Section.text field (the CDA Narrative Block):

- All elements that receivers are required by the base CDA specification to interpret. These include, but are not restricted to the following:
    - <content>
    -
- Elements that are defined in the base CDA specification but not explicitly stated as being required to interpret by the receiver:
    - <linkHtml>:
        - At a minimum must be able to be displayed as text
        - Preferably will be displayed as an active link
    - <paragraph>
    - <table>
    - styleCode values:
        - Bold, Underline, Italics
        - Ordered

Further information about expectations for display and potential workflow scenarios for the Reportability Response can be found in Volume 4 - Receiver Guidance. This

information is provided in an informative volume to assist implementers with rendering of the Reportability Response and consideration for probable workflow scenarios. Volume 4 contains example rendering of the Reportability Response using a reference stylesheet, guidance about the display of CDA header information, and suggestions for notification, alerting, routing and queuing of the Reportability Response and involved data elements.

6 REPORTABILITY RESPONSE DATA REQUIREMENTS

The following sections contain reference tables and graphic representations of the data model used in this document.

6.1 Identified Data Requirements

The table below contains an alphabetized list of data element requirements for this standard identified by eCR stakeholders.

Data Element	Data Type	Description
Authoring Agency Address Information	String	The physical address of the PHA that authored reporting specifications in the PHA system (or its intermediary)
Authoring Agency Code	Code	A code indicating the PHA that authored reporting specifications in the PHA system (or its intermediary)
Authoring Agency Contact Information	String	Contact information such as telephone, fax, email, URL for the PHA that authored reporting specifications in the PHA system (or its intermediary)
Authoring Agency Description	String	The description of the PHA that authored reporting specifications in the PHA system (or its intermediary)
Authoring Agency Name	String	The name of the PHA that authored reporting specifications in the PHA system (or its intermediary)
Date and time of eICR Receipt	Date/Time	The date and time of eICR receipt (to assist with troubleshooting and establish the elapsed time between the EHR sending the eICR and the PHA system (or its intermediary) receiving the eICR)
Determination of Reportability	Code	The determination of reportability generated by the PHA system (or its intermediary). Generally, this is expected to be Yes, No, or Maybe.
Determination of Reportability Reason	Code	A reason code indicating the reason for the reportability status
Determination of Reportability Rule	String	A rule that was involved in the determination of the reportability status
eICR CDA Document ID*	String	At a minimum, each Reportability Response should contain the unique document ID associated with the eICR that initiated its generation
eICR Encompassing Encounter ID*	String	The encompassing encounter ID from the eICR that generated the Reportability Response

*The data needed for this data element will come from the eICR that is related to the Reportability Response document.

Data Element	Data Type	Description
eICR Processing Status	Code	The status of eICR processing, including an acknowledgement of successful processing or any known errors encountered during eICR processing
eICR Processing Error Reason	Code	If the incoming eICR was not processed by the PHA system (or its intermediary), will contain the reason it was not processed
eICR Processing Warning Reason	Code	If the PHA system (or its intermediary) identifies an issue with the eICR, but is still able to process the file, this will contain those issues as a warning
Expected RCTC Version	String	The version of the RCTC that was expected by RCKMS. If populated, the EHR System Administrator should update to this version of the RCTC immediately.
External Resource Description	String	The description of link which may assist “providers” or “reporters” in understanding or investigating conditions deemed reportable by the PHA system (or its intermediary).
External Resource Category	Code	Type/category of one or more external resources
External Resource Link	String	A link which may assist “providers” or “reporters” in understanding or investigating conditions deemed reportable by the PHA system (or its intermediary)
External Resource Priority	Code	Priority given to one or more external resources
Facility Address*	String	The facility address received in the eICR
Facility Fax*	String	The facility fax received in the eICR
Facility ID Number*	String	The facility ID number received in the eICR
Facility Name*	String	The facility name received in the eICR
Facility Phone*	String	The facility phone received in the eICR
Facility Type*	String	The facility type received in the eICR
Inactive RCTC Code*	Code	Code, codeSystem, valueSet, valueSetVersion of a code that exists within the RCTC but has been labeled as inactive.
Initial Case Report Manual Initiation Reason*	String	Reason for manual initiation of the eICR
Filename of eICR*	String	The filename of the eICR (to assist with troubleshooting in the event that the eICR cannot be parsed)
Location Relevance	Code	A code indicating whether the responsible PHA is relevant because of the patient's home address, the provider facility address, or both
Manually Initiated eICR*	Boolean	If the incoming eICR was manually generated by the provider (as opposed to automatically-generated based on the existence of a trigger code from the RCTC) then this will be present.

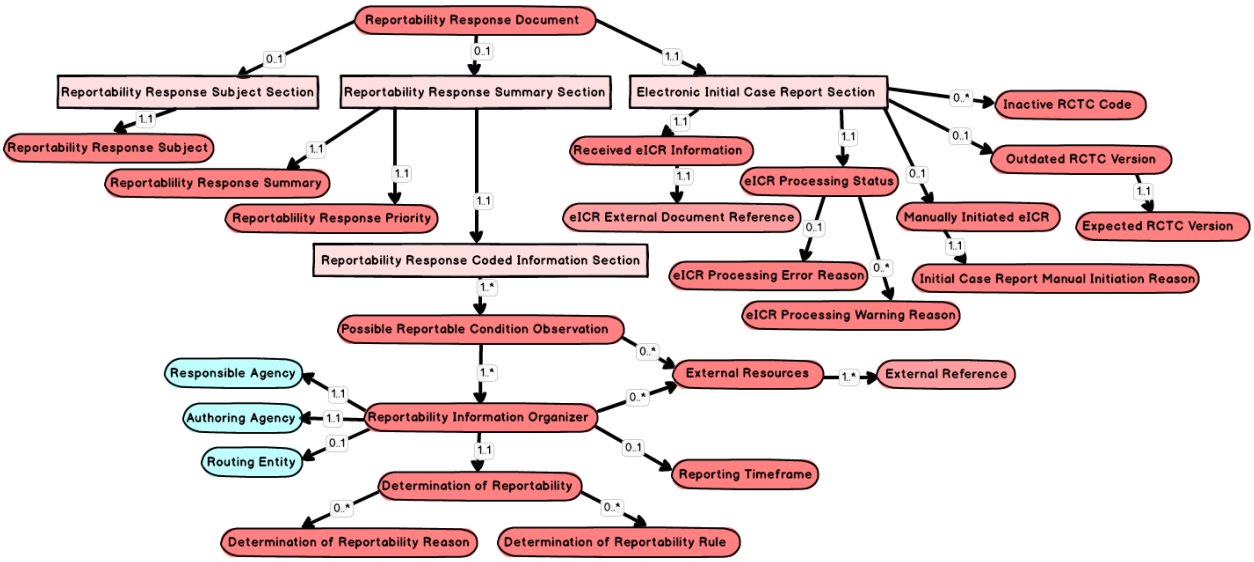
Data Element	Data Type	Description
Outdated RCTC Version*	String	If the version of the RCTC that was used to generate the eICR is outdated, the specific version used.
Parent/ Guardian Email*	String	If available, the parent or guardian email received in the eICR
Parent/ Guardian Name*	String	The parent or guardian name received in the eICR
Parent/ Guardian Phone*	String	The parent or guardian phone number received in the eICR
Patient Administrative Gender*	String	The patient administrative gender received in the eICR
Patient Birth Date*	String	If available, the patient birth date received in the eICR
Patient Email*	String	The patient email received in the eICR
Patient Ethnicity*	String	The patient ethnicity received in the eICR
Patient ID Number*	String	The patient ID number received in the eICR
Patient Name*	String	The patient name received in the eICR
Patient Phone*	String	The patient phone number received in the eICR
Patient Preferred Language*	String	The patient's preferred language received in the eICR
Patient Race*	String	The patient race received in the eICR
Patient Street Address*	String	The patient address received in the eICR
Primary Responsible Agency	Boolean	If reporting is identified for multiple PHAs by the PHA system (or its intermediary) (because the patient's residence and the provider location are in separate jurisdictions), this is an indicator of the PHA that owns follow-up on a patient with a particular reportable condition.
Provider Address*	String	The provider address received in the eICR
Provider Email*	String	The provider email received in the eICR
Provider Fax*	String	The provider fax received in the eICR
Provider ID*	String	The provider ID received in the eICR
Provider Name*	String	The provider name received in the eICR
Provider Phone*	String	The provider phone number received in the eICR
Provider Facility/Office Name*	String	The provider facility received in the eICR
Reference to eICR CDA Document*	String	At a minimum, each Reportability Response should contain the unique document ID associated with the eICR that initiated its generation

Data Element	Data Type	Description
Reportable Condition	Code	A code indicating a condition associated with an RCTC trigger code in the eICR
Reportability Response Priority	Code	A value indicating the overall priority of the Reportability Response, derived from the highest priority level of the links contained in the coded section
Reportability Response Subject	String	A succinct, human-readable narrative text that can be used as a subject header in a message queue, much like an email subject
Reportability Response Summary	String	A human-readable narrative summary that contains a reportability determination, the responsible PHA(s), and the PHA(s) that will be sent the eICR (when deemed reportable)
Reportability Response Unique Identifier	String	Each Reportability Response document should include a unique ID to allow for identification by PHA systems, EHR systems, or other interested parties
Reporting Timeframe	Code	For a given condition within a jurisdiction, the mandated timeframe in which the condition should be reported to the PHA
Responsible Agency Address Information	String	The physical address of the PHA to which reporting is legally required
Responsible Agency Code	Code	A code indicating the PHA that is responsible for follow-up on the case investigation
Responsible Agency Contact Information	String	Contact information such as telephone, fax, email, URL for the PHA to which reporting is legally required
Responsible Agency Description	String	The description of the PHA to which reporting is legally required
Responsible Agency Name	String	The name of the PHA to which reporting is legally required
Routing Entity Address Information	String	The physical address of the public health agency or other identified organization (such as an HIE) to which the eICR (if deemed reportable) and/or the Reportability Response will be routed
Routing Entity Code	Code	A code indicating the public health agency or other identified organization (such as an HIE) to which the eICR (if deemed reportable) and/or Reportability Response will be routed
Routing Entity Contact Information	String	Contact information such as telephone, fax, email, URL for the public health agency or other identified organization (such as an HIE) to which the eICR (if deemed reportable) and/or the Reportability Response will be routed
Routing Entity Description	String	The description of the public health agency or other identified organization (such as an HIE) to which the eICR (if deemed reportable) and/or the Reportability Response will be routed
Routing Entity Name	String	The name of the public health agency or other identified organization (such as an HIE) to which the eICR (if deemed reportable) and/or the Reportability Response will be routed

6.2 Reportability Response Template Hierarchy

The following diagram represents the CDA templates in the Reportability Response and the hierarchy in which they are established, including some indicators for cardinality. More specific guidance on the template hierarchy is available in Volume 2; this diagram serves as a quick reference for the template relationships.

Figure 25: Hierarchy of CDA Templates in the Reportability Response



6.3 Mapping of Elements to CDA R2 Templates

The table below maps the data elements identified by eCR stakeholders to their respective locations within the Reportability Response CDA document.

Data Element	CDA Section	CDA Mapping	CDA Data Type
Authoring Agency Address Information	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Authoring Agency/participantRole/addr	ED
Authoring Agency Code	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Authoring Agency/participantRole/playingEntity/code	CD
Authoring Agency Contact Information	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Authoring Agency/participantRole/telecom	TEL

Data Element	CDA Section	CDA Mapping	CDA Data Type
Authoring Agency Description	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Authoring Agency/participantRole/playingEntity/desc	ED
Authoring Agency Name	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Authoring Agency/participantRole/playingEntity/name	ED
Date and time of eICR Receipt	Electronic Initial Case Report Section	Received eICR Information/eICR External Document Reference/effectiveTime	TS
Determination of Reportability	Reportability Response Coded Information Section	Possible Reportable Condition/Reportability Information Organizer/Determination of Reportability	CD
Determination of Reportability Reason	Reportability Response Coded Information Section	Possible Reportable Condition/Reportability Information Organizer/Determination of Reportability/Determination of Reportability Reason/code	CD
Determination of Reportability Rule	Reportability Response Coded Information Section	Possible Reportable Condition/Reportability Information Organizer/Determination of Reportability/Determination of Reportability Rule/code	ST
eICR CDA Document ID	Electronic Initial Case Report Section	Received eICR Information/eICR External Document Reference/id	II
eICR Encompassing Encounter ID	Header	ClinicalDocument/componentOf/encompassingEncounter/id	II
eICR Processing Status	Electronic Initial Case Report Section	eICR Processing Status	CD
eICR Processing Error Reason	Electronic Initial Case Report Section	eICR Processing Status/eICR Processing Error Reason/value	CD
eICR Processing Warning Reason	Electronic Initial Case Report Section	eICR Processing Status/eICR Processing Warning Reason/value	CD
Expected RCTC Version	Electronic Initial Case Report Section	Expected RCTC Version	ST

Data Element	CDA Section	CDA Mapping	CDA Data Type
External Resource Category	Reportability Response Coded Information Section	../External Resources/code	CD
External Resource Description	Reportability Response Coded Information Section	../External Resources/External Reference/code/originalText	ST
External Resource Link	Reportability Response Coded Information Section	../External Resources/External Reference/code/text/reference	ED
External Resource Priority	Reportability Response Coded Information Section	../External Resource/priorityCode	CE
Facility Address	Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/addr	AD
Facility ID Number	Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/id	II
Facility Name	Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/name	ON
Facility Fax	Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/telecom	TEL
Facility Phone	Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/telecom	TEL
Facility Type	Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/code	CD
Filename of eICR	Electronic Initial Case Report Section	Received eICR Information/text	ED
Inactive RCTC Code	Electronic Initial Case Report Section	Inactive RCTC Code	CD
Initial Case Report Manual Initiation Reason	Electronic Initial Case Report Section	Initial Case Report Manual Initiation Reason Observation/value/originalText	ST

Data Element	CDA Section	CDA Mapping	CDA Data Type
Location Relevance	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/code	CD
Manually Initiated eICR	Electronic Initial Case Report Section	Manually Initiated eICR	CD
Outdated RCTC Version	Electronic Initial Case Report Section	Outdated RCTC Version	ST
Parent/ Guardian Email	Header	Clinical Document/record target	TEL
Parent/ Guardian Name	Header	Clinical Document/record target	PN
Parent/ Guardian Phone	Header	Clinical Document/record target	TEL
Patient Administrative Gender	Header	ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	CD
Patient Birth Date	Header	ClinicalDocument/recordTarget/patientRole/patient/birthTime	TS
Patient Email	Header	ClinicalDocument/recordTarget/patientRole/telecom	TEL
Patient Ethnicity	Header	ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode	CD
Patient ID Number	Header	ClinicalDocument/recordTarget/patientRole/id	II
Patient Name	Header	ClinicalDocument/recordTarget/patientRole/patient/name	PN
Patient Phone	Header	ClinicalDocument/recordTarget/patientRole/telecom	TEL
Patient Preferred Language	Header	ClinicalDocument/recordTarget/patientRole/patient/languageCommunication	CD
Patient Race	Header	ClinicalDocument/recordTarget/patientRole/patient/raceCode	CD
Patient Street Address	Header	ClinicalDocument/recordTarget/patientRole/addr	AD
Primary Responsible Agency	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/code/qualifier	CD

Data Element	CDA Section	CDA Mapping	CDA Data Type
Provider Address	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/representedOrganization/addr	AD
Provider Email	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[mailto:]	TEL
Provider Facility/Office Name	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/representedOrganization/name	ON
Provider Fax	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[fax:]	TEL
Provider ID	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/id	II
Provider Name	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/assignedPerson/name	PN
Provider Phone	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[tel:]	TEL
Reference to eICR CDA Document	Electronic Initial Case Report Section	Received eICR Information/eICR External Document Reference/text/reference	ED
Reportable Condition	Reportability Response Coded Information Section	Possible Reportable Condition Observation/value	CD
Reportability Response Priority	Reportability Response Summary Section	Reportability Response Priority/value	ED
Reportability Response Subject	Reportability Response Subject Section	Reportability Response Subject/text	ED
Reportability Response Summary	Reportability Response Summary Section	Reportability Response Summary/text	ED
Reportability Response Unique Identifier	Header	ClinicalDocument/id	II
Reporting Timeframe	Reportability Response Coded Information Section	Possible Reportable Condition/Reportability Information Organizer/Reporting Timeframe/value	CD

Data Element	CDA Section	CDA Mapping	CDA Data Type
Responsible Agency Address Information	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/addr	ED
Responsible Agency Code	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/playingEntity/code	CD
Responsible Agency Contact Information	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/telecom	TEL
Responsible Agency Description	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/playingEntity/desc	ED
Responsible Agency Name	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/playingEntity/name	ED
Routing Entity Address Information	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/addr	ED
Routing Entity Code	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/playingEntity/code	CD
Routing Entity Contact Information	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/telecom	TEL
Routing Entity Description	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/playingEntity/desc	ED
Routing Entity Name	Reportability Response Coded Information Section	Possible Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/playingEntity/name	ED

APPENDIX A — ACRONYMS AND ABBREVIATIONS

APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
C-CDA R2.1	Consolidated CDA Templates for Clinical Notes, DSTU 2.1
C-CDA R2.1 CG	C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 1
CCD	Continuity of Care Document
CDA R2	Clinical Document Architecture (Release 2)
CDC	Centers for Disease Control and Prevention
CPT	Current Procedural Terminology
CSTE	Council of State and Territorial Epidemiologists
EHR	electronic health record
eCR	electronic case reporting
eICR	electronic initial case report
eICR IG	Public Health Case Report, R2, Standard for Trial Use Release 1.1
EMR	electronic medical record
EVN	event
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTML	Hypertext Markup Language
ICD	International Classification of Diseases
IG	implementation guide
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standard Development Organisation
ITI	information technology infrastructure
LOINC	Logical Observation Identifiers Names and Codes
NA	not applicable
NI	no information
NUCC	National Uniform Claim Committee
OID	object identifier
OTH	not an element in the value domain
PHER HL7	HL7 Public Health and Emergency Response Work Group
PDF	Portable Document Format

RCTC	Reportable Condition Trigger Codes
RFC	request for comment
RIM	Reference Information Model
RR	Reportability Response
RR R1S1	Reportability Response Release 1 STU Release 1.0
S&I	Standards and Interoperability
Sdtc	Structured Documents Technical Committee (namespace identifier)
SDWG	HL7 Structured Documents Working Group
SNOMED CT	Systemized Nomenclature for Medicine – Clinical Terms
STU	Standard for Trial Use
UNK	unknown
URI	uniform resource identifier
URL	uniform resource locator
URN	uniform resource name
XML	eXtensible Markup language
XPath	XML Path Language

APPENDIX B — EXTENSIONS TO CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. These extensions are described in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance. For a full list of approved CDA extensions, see: CDA_R2_Extensions.

Extensions used in this guide include:

sdtc:raceCode	The raceCode extension allows for multiple races to be reported for a patient.
sdtc:ethnicGroupCode	The ethnicGroupCode extension allows for additional ethnicity groups for the recordTarget or subjectPerson.
sdtc:deceasedInd	The deceasedIndextension (= “true” or “false”) in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
sdtc:deceasedTime	The deceasedTime extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
sdtc:dischargeDispositionCode	The dischargeDispositionCode extension allows the provider to record a discharge disposition in an encounter activity.
sdtc:signatureText	The signatureText extension provides a location in CDA for a textual or multimedia depiction of the signature by which the participant endorses and accepts responsibility for his or her participation in the Act as specified in the Participation.typeCode. Details of what goes in the field are described in the HL7 Implementation Guide for CDA® Release 2: Digital Signatures and Delegation of Rights, Release 1.
sdtc:valueSet	The valueSet extension allows the implementer to reference a particular value set from which a code was drawn.
sdtc:valueSetVersion	The valueSetVersion extension allows the implementer to reference a specific version of a value set.

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- All extensions are optional. An extension may be used, but need not be under this guide.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.

- The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) shall be urn:hl7-org:sdtc.
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element shall appear in the XML where the expected RIM element of the same name would have appeared.

