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

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HL7 Standard for Trial Use (STU)

Volume 1 – Introductory Material

Sponsored by:
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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.

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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 Reportability 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[2] conditions (infectious and non-infectious) is required by law in all States and Territories in the United States, and constitutes the act of reporting. This reporting does not equate to the patient having a condition or meeting a case definition (definitively being "a case") but indicates events of public health interest. 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. Clinical care is authorized to make disclosures to public health by sending identifiable reports of public health events under the public health exemption of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

In addition to supporting critical public health functions in State, Local, and Territorial Public Health Agencies (PHAs), referring to specific governmental public health organizations, 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. For the purposes of the implementation guide (IG), the term "public health" refers to Public Health Agencies, their delegates, and their intermediaries. Together, these eCR advances can significantly lower healthcare provider reporting burden while significantly 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 conditions. 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 for reporting.

The Reportability Response

The automated reporting of information from healthcare to public health can bring many benefits, but it also brings new capabilities and needs for information to flow

[1] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=436
[2] In this guide, the term reportability is used to indicate "the quality or state of being reportable or not."

from public health to clinical care. For some time, clinical care providers have expressed the 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 communication"[3],[4],[5],[6],[7] 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 conditions and their patients. These are some of the purposes of the Reportability Response document.

There are other needs for the Reportability Response in eCR. Healthcare organizations will 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 on important public health conditions for which they may have just submitted a report.
- Frequently, clinical support staff or Infection Control Practitioners (ICPs) are responsible for following-up on reportable conditions and ensuring that all reporting is accomplished, as well implementing relevant transmission mitigation procedures within their healthcare facility.
- EHR system 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 Reportability Response is designed to have one Reportability Response created for each eICR and to be shared with the clinical care organization that created the eICR. The Reportability Response can also be shared with a Public Health Agency(ies)(PHA) that has relevant reporting requirements (a responsible Public Health Agency) that wants to use it to monitor the reporting process and know what has been conveyed to clinical care organizations and other PHAs.

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[3] Birkhead, Guthrie S., Klompas, Michael, Shah, Nirav R., "Uses of Electronic Health Records for Public Health Surveillance to Advance Public Health," *Annual Review of Public Health*, Vol. 36:345-359. March, 2015.

[4] Dixon, Brian E., Gamache, Roland E., Grannis, Shaun J., "Towards public health decision support: a systemic review of bidirectional communications approaches," J AM Med Inform Assoc, 20(3):577-83, May 1, 2013.

[5] Magnuson, J.A., Fu Jr., Paul, C., Public Health Informatics and Information Systems, *Springer-Verlag*, London, 2013.

[6] Loonsk., John W., Testimony to National Committee on Vital and Health Statistics (NCVHS), Hearing on Public Health Data Standards, National Center for Health Statistics, November 12, 2013.

[7] Holt, E., Roberts, J., Loonsk, J., "The eICR; A National Standard for Public Health Case Reporting," Public Health Informatics Conference, 2015.

Sharing the Reportability Response with clinical care can serve several functions including to:

- Communicate the reportability status, for the responsible PHA(s), of each condition included in the eICR
- Identify who (a PHA or an intermediary) prepared the Reportability Response
- Indicate whether the eICR has been sent to one or more PHA(s)
- Identify which PHA(s) has/have been sent the eICR
- Provide contact information for the responsible PHA(s)
- Provide suggested or required clinical follow-up activities from the responsible PHA(s), including any additional reporting needs or infection control activities
- Provide access to clinical support resources suggested by the responsible PHA(s) for identified reportable conditions
- Confirm eICR receipt and processing

Some PHA's have indicated that they also want copies of Reportability Responses (when they have not generated them) for a multitude of reasons including but not limited to:

- As an indication of other PHAs that may be involved;
- To receive what was sent on their behalf by an intermediary;
- To monitor and audit decision support algorithm effectiveness and implementation; and
- To monitor EHR reporting patterns relative to both triggering implementation and condition trends.

Determination of Reportability

Reportability indicates the quality or state of a possible case/event being reportable to one or more PHA. It does not, in itself, represent the clinical diagnosis of a possible condition nor the conclusion that a possible case/event fully meets a public health case definition. Reportability is based on information at a given point of time and, resultantly, reportability status can change when additional or different information becomes available.

Decision support systems that provide a determination of reportability of a possible condition produce results that may fall into a number of types. One or more of these reportability determinations may be present in the Reportability Response based on the possible condition(s) in the eICR being assessed.[8]

[8] This value set will be dynamically bound - meaning that, if needed, it can be updated after the IG is published.

The values that can currently be used for the ***Determination of Reportability*** are described below.

A possible condition is:

- ***Reportable*** - The information provided meets reporting criteria for an associated PHA.

A possible condition:

- ***May be Reportable*** - The information provided may meet reporting criteria if additional information is provided. The Reportability Response will also be able to share the information needed to definitively determine reportability.

A possible condition is:

- ***Not Reportable*** - The information provided conclusively does not meet reporting criteria.

Some decision support systems may not be able to fully differentiate between possible conditions that are ***Not Reportable*** and those that ***May be Reportable*** if additional information is provided. In these circumstances there may only be a reportability determination of:

- ***No Reporting Rule Met*** - The information provided does not meet reporting criteria or may meet reporting criteria if additional information is provided.

The determination of ***No Reporting Rule Met*** may be provided for a possible condition or for all conditions in the eICR.

External Content and Resources

In order to support several functions it is intended that Reportability Response will be automatically created as rapidly as possible after receipt and decision support processing of an eICR. Resultantly, any information to be contained in a Reportability Response needs to be available before the document is created. At times it will be desirable for PHAs to provide access to information, instructions, guidance, contact information, or follow-up activities in the Reportability Response in the context of a ***Reportable*** or ***May be Reportable*** condition.

In the Reportability Response, this "external" content will be found in ***External Resources*** which may contain either succinct condition-specific human readable narrative content (***External Resource Description***) for presentation to *Providers/Reporters* or such narrative and links (***External Resource Link***) to external content or systems accessible through public health web sites and related information systems.

The Reportability Response provides the ability for PHAs to provide these ***External Resources*** to decision support systems while maintaining most of the material externally and adding or changing content in association with dynamic situations like an outbreak or other public health event. The Reportability Response can provide this specific information and follow-up activities (like supplemental data reporting) to *Providers/Reporters* in the context of the patient, a patient's condition(s), and the relevant PHA(s).

EHR vendors will be able to manifest the links in ***External Resources*** in different ways in keeping with the capabilities of their platform. One approach is to render the link as active, using highlighted or underlined text that can be clicked to provide the information or access the external system through a web browser. Some EHR vendors and legacy products are not able to provide active links and may, as a result provide a full link address (URI or URL) that can be copied and pasted into a web browser.

Some EHR vendors and clinical care sites use "white lists" to insure that links are safe and appropriate for use in clinical care settings. The links in the Reportability Response will come from a limited set of government Internet addresses, so the domains will be readily available for use in such "white lists." They will be from trusted sources and through the Reportability Response, will be conveyed under security capable of protecting sensitive patient information. Such access to clinician oriented content on PHA websites is an expected part of bidirectional communication between public health and clinical care.

Each ***External Resource*** (text or text and link) is associated with an ***External Resource Category*** that is used to order the external resources in the narrative presentation for viewing by *Providers / Reporters*. The possible categories[9] in their intended order of presentation are:

- Outbreak- or Cluster related
- Additional reporting needs
- Additional detection and/or laboratory testing needs
- Treatment and/or prevention
- PHA contact info
- Additional resources

External Resources (text or text and link) are also each associated with an ***External Resource Priority*** which is displayed in the Reportability Response narrative and identifies the urgency of the information or action expressed. Possible priorities[10] include:

- Immediate action required
- Action required
- Immediate action requested
- Action requested
- Information only

Options in which the term "required" is included are intended to only be used when that information or action directly relates to a specific statutory requirement.

[9] This value set will be dynamically bound - meaning that, if needed, it can be updated after the IG is published.

[10] This value set will be dynamically bound - meaning that, if needed, it can be updated after the IG is published.

Because Reportability Responses are intended to be automatically created and may include more than one reportable condition, there is no opportunity for the manual assignment of an overall Reportability Response priority or urgency. To address the need for a document level priority and urgency, ***Reportability Response Priority*** will be populated with either 1) the highest priority of any included ***External Resources*** or 2) the highest priority of included reportable conditions based on a separate, jurisdictionally developed priority list.

Error and warning descriptions in *eICR Processing Status*

Reportability Response errors and warnings are intended to communicate with those who act in the role of *EHR System Administrator*. Errors and warnings will come from the processing of the eICR. Some may come from an integration broker, some from decision support, and some from a surveillance system.

For the purposes of this IG, errors have been defined as situations where the relevant eICR was not processable and warnings are situations where the eICR was processable, but there was an issue(s). As such, Reportability Responses with warnings should be processed and, as appropriate, visualized for *Providers / Reporters* and be shared with *EHR System Administrators* so they may handle warning issues. Reportability Responses with one or more errors will not represent processed eICRs, so while clinical personnel may need to be informed of unsuccessful reporting, the *EHR System Administrator* will need to help resolve the related issues.

Possible ***eICR Processing Status*** values for errors and warnings at the time of publication[11] include:

- eICR processed
- eICR was processed - with a warning
- eICR was processed - with a severe warning
- eICR was not processed - error

Possible ***eICR Processing Status Reason*** values include brief explanations[12] of errors and warnings:

- eICR was not processed due to an error of: fatal problem with the eICR that was received
- eICR was not processed due to an error of: an ongoing server problem
- eICR was not processed due to an error of: significant content or format issues
- eICR was processed with a severe warning of: invalid eICR identifier
- eICR was processed with a severe warning of: required data not found
- eICR was processed with the warning of: content or format issues

[11] This value set will be dynamically bound - meaning that, if needed, it can be updated after the IG is published.

[12] This value set will be dynamically bound - meaning that, if needed, it can be updated after the IG is published.

- eICR was processed with the warning of: inactive RCTC code
- eICR was processed with the warning of: outdated RCTC version

There are two types of warnings that relate to the Reportable Condition Trigger Codes (RCTC). First, the RCTC version identified as being used in the eICR may be outdated if it does not match the expected (current) version on receipt. The ***eICR Processing Status Reason Detail*** template will hold the details of the outdated and expected versions of the RCTC.

Second, if any of the individual trigger codes used to generate the eICR are codes that are marked as inactive in the latest version of the RCTC the ***eICR Processing Status Reason Detail*** template will hold this inactive RCTC code and the details of the current and expected version of the RCTC that should be in use.

Much more detailed error and warning content that may be generated from eICR validation tools can also be conveyed in the Reportability Response. This information, when available, is stored in the ***eICR Validation Output*** template, and may use differing definitions for errors or warnings than those described above, such as those defined by HL7 CDA Schema, Schematron or other sources, but can provide developers and implementers with fine grained information on eICR construction issues.

Linking Reportability Responses to eICRs and linking eICRs to each other

Any given patient encounter may lead to the generation of more than one eICR and each eICR has a Reportability Response. Each Reportability Response can be linked to its associated eICR through the use of the eICR unique identifier. In the eICR it is identified as id and the same unique eICR identifier is found in ***Received eICR Information/eICR External Document Reference/id*** in the associated Reportability Response.

It is also important to be able to link eICRs and Reportability Responses for the same patient encounter. For these purposes, each eICR will have a ***parentDocument.setId*** and a ***parentDocument.versionNumber.*** The ***setID*** should be the same for each eICR that comes from the same patient encounter and the ***versionNumber*** should increment for each eICR that is generated from the same patient encounter. These can be helpful in linking eICRs and Reportability Responses for the same possible case. In general, subsequent eICRs for the same patient encounter should be considered as replacements, rather than addenda, to the eICRs that preceded them for that patient encounter.

It is also important to understand that each Reportability Response will have its own ***unique id***, ***setId***, and ***versionNumber*** that is separate from those of the eICR. Because the Reportability Response is secondary to the eICR, we have emphasized the use of eICR identifiers. It should also be noted that different EHR vendors define encounters differently in the CDA and care should be taken to work around these variances.

1.2 Audience

This IG provides public health systems developers guidance for implementing functionality used by public health to generate a Reportability Response. The Reportability Response would be shared for processing with the PHA if requested (and if they are not originating it). This IG also provides EHR vendors and clinical implementers with guidance for receiving and processing Reportability Responses. The IG will be instructive to healthcare providers, public health staff, analysts, and health information exchange organizations among others. Users of this IG must be familiar with the details of the HL7 CDA R2 document construction and the *Consolidated CDA Templates for Clinical Notes, DSTU 2.1*[13] (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 IG is organized into four volumes. Volume 1 contains primarily narrative text describing this IG, whereas Volume 2 contains normative CDA R2 template definitions. Volumes 3 and 4 contain informative guidance for the creator 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 includes the eCR context flow diagram, 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 IG. 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 IG.

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.

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

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: Creator 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 certain events of public health importance, including certain infectious and non-infectious related conditions and events, and may sometimes require reporting of these events on suspicion. After receipt of that information, PHAs will conduct investigations and determine case classification. The reporting of these events to State, Local, and Territorial PHAs is considered case reporting. 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 PHA.[14]

Previous efforts to develop standards for the exchange of case data (also referred to as reportable event data) between healthcare and public health have been hampered by inter-organizational exchange issues and 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 conditions 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 Reportability Response standard is to define a singular standard that can be used for all conditions and in all jurisdictions for interorganizational exchange between healthcare and public health settings. Stage 3 of the CMS EHR Incentive Program (Meaningful Use) has identified electronic public health case reporting as a Public Health/Registry reporting menu option for clinical reporters. This IG also has a goal to contribute to consistent bi-directional exchange of information 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 IG provides a path to capture supplemental data from clinical care when it is needed for a condition or required by PHA 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 resources.

Several PHAs 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 case reports in their integrated surveillance system 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 IG builds on experience, specifications and lessons learned from the previous releases of the HL7 Implementation Guide for CDA Release

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

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 Condition Trigger Codes.

1.5 Scope of the Implementation Guide

The following areas are in scope for this IG:

- The data elements to be shared by public health in a Reportability Response
- A description of the stakeholders, actors and use cases
- The definition of a standard document format including structure and content (i.e., vocabulary) in HL7 CDA R2 format
- Guidance for the generation and sending of a Reportability Response (informative guidance and critical data for these workflows is provided in Volume 3 of this IG)
- Guidance for clinical care and EHR vendors to receive a Reportability Response and support its use, when appropriate, by *Providers*, *Reporters*, and *EHR System Administrators* (Informative guidance and critical data for these workflows are provided in Volume 4 of this IG)
- Guidance for PHAs to receive a Reportability Response and support its use, when they have requested to receive it (Informative guidance and critical data for these workflows are provided in Volume 4 of this IG)

The following areas are out of scope for this IG:

- The specific methods 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 IG)
- The creation, sending, receipt, and acknowledgement of a non-eICR case report (i.e., case reports in other formats), or lab reports
- The definition of specifications and guidelines on reportable event criteria (e.g., defining reportable conditions). This IG does not define the reporting criteria or the potential data elements that a PHA may want in a complete report
- The description of the process for PHAs to perform follow-up activities, including investigations, case management and case 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 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
- A human readable short summary of the Reportability Response which could be used as a work queue or in-box subject header inside of EHRs
- A human-readable summary of narrative text describing the name of the relevant reportable condition(s), the PHA(s) sent the report, and resources that provide information for *Providers* and *Reporters* to take any necessary next steps
- An indication of the need for (or lack of need for) action by the healthcare provider or their designee
- Contact information for the patient and provider in question
- Contact information for the responsible PHA(s)

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

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

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 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 to 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 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 Electronic Case Reporting

Stakeholders	Description
Clinical Care Provider	Any supplier of a healthcare service, i.e., a person or organization that furnishes 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 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 IG, EHR can also be interpreted to refer to applications that some vendors may call an 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 PHA regarding case reporting. An intermediary may be acting on behalf of either the healthcare organization as a business associate or public health as an authorized agent. Examples include a Health Information Exchange (HIE) organization, a clinical trust and exchange network, or a shared infrastructure and routing platform like that of APHL Informatics Messaging Services (APHLAIMS)
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.
Patient	A person receiving or registered to receive medical treatment. Related to electronic case reporting, public health personnel may contact a patient to collect additional information for public health case management/investigation.
Public Health Agency (PHA)	A governmental entity at the federal, state, territorial, local or tribal level that protects and improves the health of families and communities through promotion of healthy lifestyles, research for disease and injury prevention and detection and control of infectious diseases. Specifically, for electronic case reporting, this entity is individually legally entitled (not using someone else's authority) to establish public health case reporting requirements and receive case reports.
Public Health Decision Support (PHDS)	A service that provides clinical care or public health personnel with information or knowledge to assist with decision making. For electronic case reporting, it may provide information 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), Electronic Support for Public Health (ESP), or other Public Health Decision Support (PHDS) solutions.
Public Health Information System	Jurisdictional information systems that may, among other things, receive public health case reports. These systems may include public health registries and public health surveillance systems.
Public Health Reporter	Clinical or administrative staff that support the provider or an infection control practitioner, with delegated responsibility for reporting to public health. Specifically, for electronic case reporting, this person may serve as a possible recipient of the Reportability Response and provide follow-on information to PHA if requested
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 IG specifies the document to pair with each eICR for the purposes of communicating reportability and providing other relevant information to clinical care organizations (and providing to PHAs, if generated by an intermediary and requested).

Future work on eCR standards may include:

- Developing additional HL7 standards using FHIR technology to support the eICR, Reportability Response CDA document standards and appropriate triggering/decision support standards
- Developing FHIR resources, profiles, and extensions for common supplemental case questions and data that can be used by programs and PHAs to complement, when needed, data in the eICR
- Specifying and advancing a) optional templates and other data conveyance that may supplement an eICR, and b) form standards such as IHE RFD / HL7 Structured Data Capture to record other 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, the communication, updating and use of trigger codes and decision logic for public health decision support services to ease implementation and improve the sensitivity, specificity, and comparability of reporting from clinical settings
- 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 communicating data to public health and to allow for more efficient and standardized implementation of public health systems and infrastructure
- Advancing additional standards, as needed, to support public health investigations of outbreaks and events
- Developing more robust format and exchange methodologies/standards for the Reportable Condition Trigger Code list

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_2017DEC _Vol1_Introductory_Material.docx	IG Introductory Material	Chapter 1 Chapter 4 Chapter 5 Chapter 6 Appendix A Appendix B	Chapter 2 Chapter 3
CDAR2_IG_PHCR_R2_RR_D1_2017DEC _Vol2_Templates_and_Supporting_Material.docx	IG Template Library and Supporting Material	Templates Appendixes	Examples
CDAR2_IG_PHCR_R2_RR_D1_2017DEC _Vol3_Creator_Guidance.docx	Informative creator guidance for generating narrative	n/a	Guidance file
CDAR2_IG_PHCR_R2_RR_D1_2017DEC _Vol4_Receiver_Guidance.docx	Informative receiver guidance for visualization of narrative	n/a	Guidance file
CDAR2_IG_PHCR_R2_RR_D1_2017DEC_ Sample.xml	Reportability Response CDA XML sample file	n/a	Sample file
GForge link: PHCASERPT RR GForge GForge SVN url: http://gforge.hl7.org/svn/pher/trunk/PHCASERPT_RR/	XML and Related files (Schematron, sample, html, stylesheet) GForge account required. See GForge SVN Access Info for details.	n/a	XML and related files
GForge link: CDA Schema	CDA Schema	n/a	CDA Schema

2 USE CASE FOR eCR AND THE REPORTABILITY RESPONSE

The scope of this IG 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 eCR Context Flow Diagram

The diagram below shows the context for the overall flow of eCR, including where creation of the Reportability Response fits within the flow.

The left side of the eCR Context flow diagram shows (Figure 1) the generation and sending of the eICR including:

- The eICR is manually initiated by a provider.
- The eICR is automatically initiated based on a comparison of electronic health record data for an encounter against codes in a "trigger code file" provided by public health. This method requires a second level of decision support to determine relevant PHAs and make a determination on reportability.
- The eICR created and sent from an EHR system.
- The eICR created in an EHR and sent through a designee of clinical care, such as an HIE or trust network.

The center section, "Functions of eCR Decision Support and Interorganizational Exchange", shows the functions that need to occur in order for a Reportability Response to be constructed and routed appropriately. Some of these functions could be operationalized by clinical care, public health, or one or more intermediaries (such as health information exchange organizations, clinical trust networks, or other shared services platforms).

"Determine Reportability for eICR Condition(s) for each Responsible Agency(ies)" is a function to determine if possible condition(s) in the eICR meet jurisdictional reporting requirements and to which responsible agency(ies) the eICR should be sent. This function could be met by:

- A centralized decision support service, such as RCKMS, that is designed to include reporting specifications for all PHAs and all conditions
- A localized decision support service such as ESP
- Manual inspection (not recommended) at a PHA in the absence of an automated approach

Once generated, the Reportability Response will be sent to the eICR originating clinical care organization and possibly to a PHA, if generated by an intermediary. Once received by clinical care, the following may take place:

• The Reportability Response will be parsed and routed to the appropriate recipient

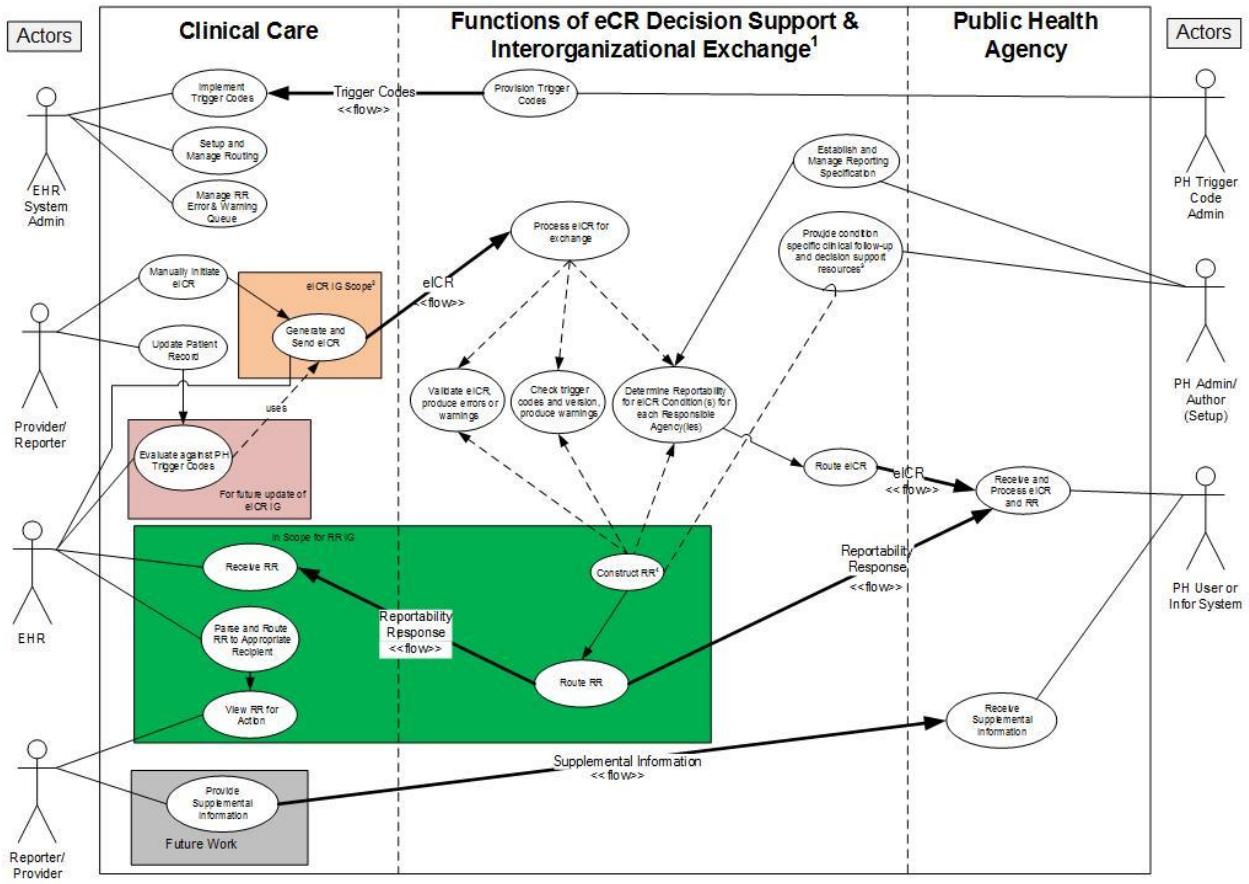
• The Reportability Response could be reviewed for action by a provider and/or a reporter

• Errors and warnings associated with the Reportability Response should be managed

The right side of the eCR Context flow diagram shows:

- The eICR is received by the PHA (either directly or from an intermediary such as the APHL AIMS platform and/or an HIE).
- The PHA receives the Reportability Response from an intermediary, such as the APHL AIMS platform or an HIE.
- The PHA receives Supplemental data from clinical care (future scope).

Figure 1: Electronic Case Reporting Context Flow Diagram Reporting to a Public Health Agency



[1] Some or all of these functions may be operationalized by:
- one or more intermediaries (such as health information exchange organizations, clinical trust networks, or other shared services platform);
- clinical care; and/or
- public health agencies,
under the authority of clinical care, public health or a combination thereof.

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 or clinical staff 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 information and data (e.g., demographic, clinical, laboratory, pharmacy) to generate a conformant 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 public health system may be a single stand-alone system or a component-based architecture. The public health system may interface with other systems that are used to help create, populate, or transmit the Reportability Response to clinical care.
- The public health 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 IG.
- The public health 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 with those that they connect to. There may be several “hops” between the EHR system and the public health information system. Where possible, Reliable Messaging will be helpful for supporting this transport.
- 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 (i.e., RCTC – currently available at PHIN VADS), is implemented and accessed by the EHR system to match against encounter records.
- The EHR has implemented the ability to create an eICR initiated by the following methods:
    - An automated match of coded information in a patient record for an encounter to a set of trigger codes within the EHR
    - Manual provision of patient information by a provider to trigger a report to public health
- The EHR system has implemented the ability to include all appropriate information (e.g., data elements and terminology) in the eICR.
- The receiving system receives and processes the eICR.
- A record of an eICR sent from the EHR to public health is stored in a log within the authoring system at the EHR.
- 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 associated with the appropriate patient encounter and managed for any applicable follow-on processing 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 to the clinical care provider has been stored in a log at the PHA and/or an 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.

- The Reportability Response has been correlated to the appropriate eCIR at the PHA.
- The Reportability Response/eCIR pairing has been correlated with any potentially associated electronic lab reports.
- The eICR associated with any Reportability Response can be used by the PHA Information System.
- The Reportability Response can be rendered at the PHA for a user upon request.

2.5 Actors and Roles

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

Actor	Role
Provider (Clinical care provider)	• Has clinical responsibility for the patient in question • May be the clinician of record for the patient • Has responsibility for reporting to public health as appropriate • Update information in the EHR System about the patient • Serve as a possible recipient of the Reportability Response • The provider and the reporter may be the same person • If desired, initiate sending of eICR and provide reason for initiation (manual initiation) • Either directly or through a *Reporter*, provide follow-on information to PHA if requested
EHR	• 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 public health • Receive, route, and render the Reportability Response from public health • Make eICR available with associated Reportability Response when requested • Maintain a work queue (e.g., inbox) for Reportability Responses that require follow-on action
EHR System Administrator	• Configure any routing and/or applicable follow-on processing for Reportability Response requiring action with the receiving EHR system
Reporter (Public Health Reporter)	• May be a clinical or administrative staff person that supports the provider or an infection control practitioner • May have delegated responsibility for reporting to public health • Executes reporting responsibilities • Serve as a possible recipient of the Reportability Response • The provider and the reporter may be the same person
PHA User or Information System	• Receive and process eICR from EHR system or intermediary • If requested, receive and process Reportability Response • Receive and process supplemental information provided by Provider or Reporter • Use the information contained in the PHA system to carry out public health surveillance and investigation activities
PH Admin/Author (Setup)	As set-up steps for public health decision support, • Establish and manage reporting specifications • Provide condition-specific clinical follow-up and other decision support resources
PH Trigger Code Admin	• Identify and maintain set of trigger codes to be used in an EHR for comparison of electronic health record data for an encounter against these codes • Publish Trigger Code Set (on a routine schedule and/or for emergent situations)

Several functions can be supported by different actors to fulfill the following roles:

- Receive and process eICR from EHR system or other intermediary to:
  - Validate eICR
  - Check for valid trigger codes and current version
  - Determine reportability status using predefined jurisdiction- and condition-specific rules
- Send the eICR and Reportability Response (when requested) to identified PHAs based on public health decision support
- Construct the Reportability Response
- Send the Reportability Response to the EHR system or its intermediary

The actors for "Functions of eCR Decision Support and Interorganizational Exchange" (as identified in the eCR Context flow diagram) could be :

- one or more intermediaries (such as health information exchange organizations, clinical trust networks, or other shared services platforms);
- clinical care; and/or
- public health agencies,

under the authority of clinical care, public health or a combination thereof.

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 Than One Reportable Condition to One or More Than One PHA

In this scenario, the Reportability Response will communicate, for one or more PHAs, which condition(s) is/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 an intermediary), and a public health decision support system confirms if it meets a PHA's reporting requirements in order to indicate that reporting to the specific PHA is necessary.

The eICR and, at times, the Reportability Response are shared with the appropriate PHA(s) (if they did not originate it), and the Reportability Response is shared with the originating clinical care organization. Inside of the clinical care organization, the Reportability Response is associated with the appropriate patient encounter and provides status of legally required reporting. For a Reportability Response that

requires action, the EHR may also queue (or be noted via a secure e-mail inbox) the action to notify the *Provider* of the condition(s) and applicable requested follow-on processing. In unusual circumstances, one potential action might be to alert the provider. Based on internal workflows, at times, the Reportability Response may need to be directly routed to a clinical care staff *Reporter's* work queue, or will be forwarded to them 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 not all data that are needed to determine reportability are 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 an intermediary), and a public health decision support system uses the appropriate set of rules, but reportability cannot be confirmed for the relevant PHA(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 Reportability Response may include guidance for the *Provider* or *Reporter* about how to provide the missing data (e.g., by direct follow-up with the relevant PHA, as part of a supplemental data request, or by manually initiating 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 trigger an eICR for reportable conditions, but specific reporting rules can vary between PHAs. There are circumstances where an eICR will be determined not to be reportable because it is not on the list of reportable conditions for the relevant PHA or the information provided at the time of this report does not meet reporting criteria.

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 an intermediary), and a public health decision support system uses the appropriate set of rules, but no reportability is determined for the relevant PHA(s).

The related eICR is processed based on PHA input recorded in decision support (if the eICR is being processed by an intermediary). The Reportability Response may, or may not, be shared with the appropriate PHA(s) also based on PHA input (and if they are not originating it). The Reportability Response will always be shared with the involved clinical care organization to "close the loop" and for audit purposes on the eICR that

had been shared, but it is recommended neither *Providers* nor *Reporters* receive notification unless they specifically ask for it.

2.6.4 Reporting Issue

All eICRs are intended for machine processing and archiving 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 for public health assessment.

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 technical 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. In situations where there is a decision support intermediary and the eICR can not be processed, the appropriate PHA(s) would not be able to be determined. In the situation where the eICR can be processed but a warning was identified, the Reportability Response would be shared with the PHA if requested by the PHA. In situations where the eICR can not be processed, the relevant PHA may not be able to be determined. If the relevant PHA(s) can be determined, the Reportability Response will be shared, for PHAs that want to receive it, as an early indication that there may be something on which to follow up.

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:

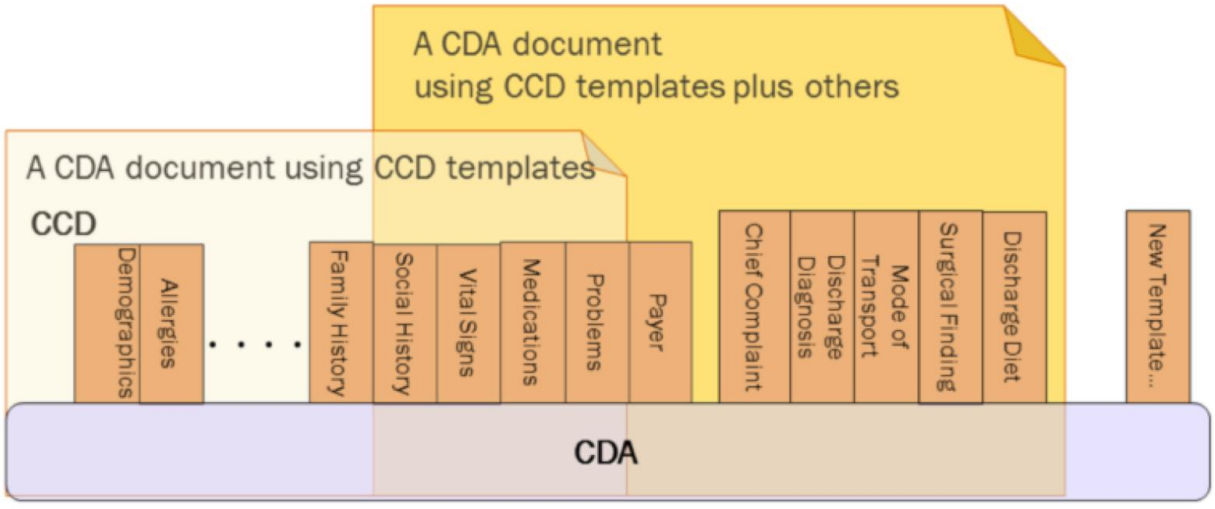
- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

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 2: 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 IG. They reduce the need to repeat constraints in templates that use the common set.

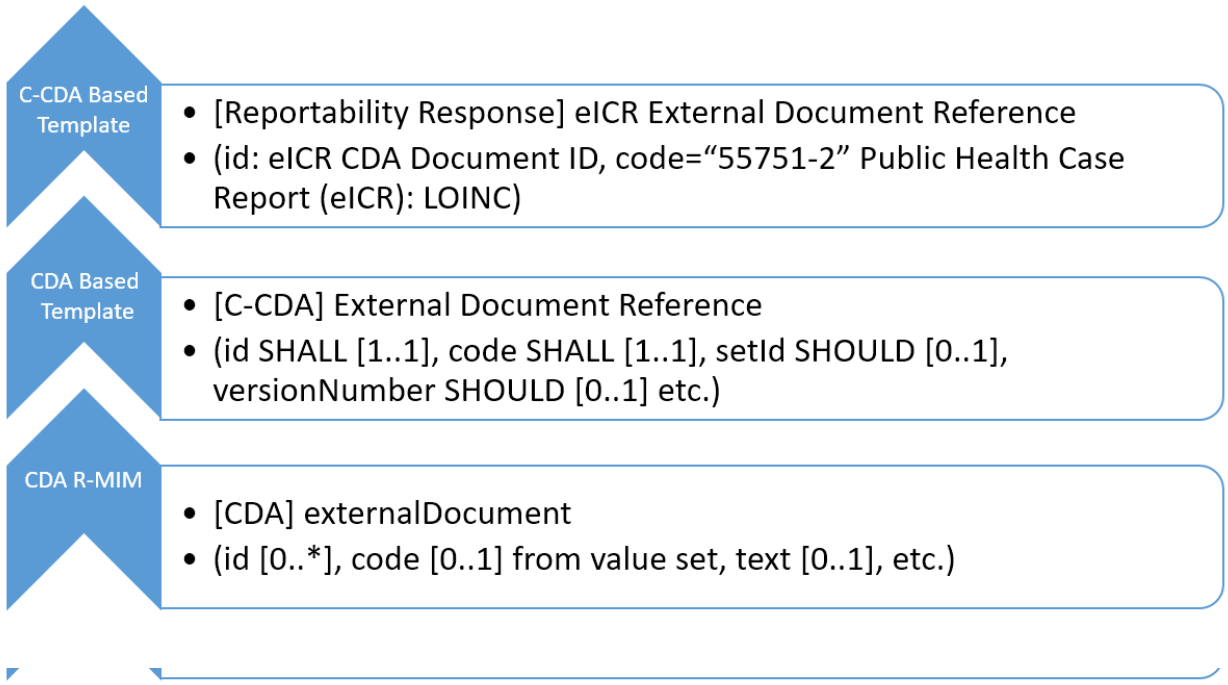
A CDA R2 IG (such as this one) includes references to those template versions that are applicable. A CDA R2 instance populates the template identifier (templateId) field where it wants to assert conformance to a given template version. On the receiving side, the recipient can then test the instance for 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 3: 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 4: 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*[15] 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.

[15] 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 IG.

4.1.1 Templates and Conformance Statements

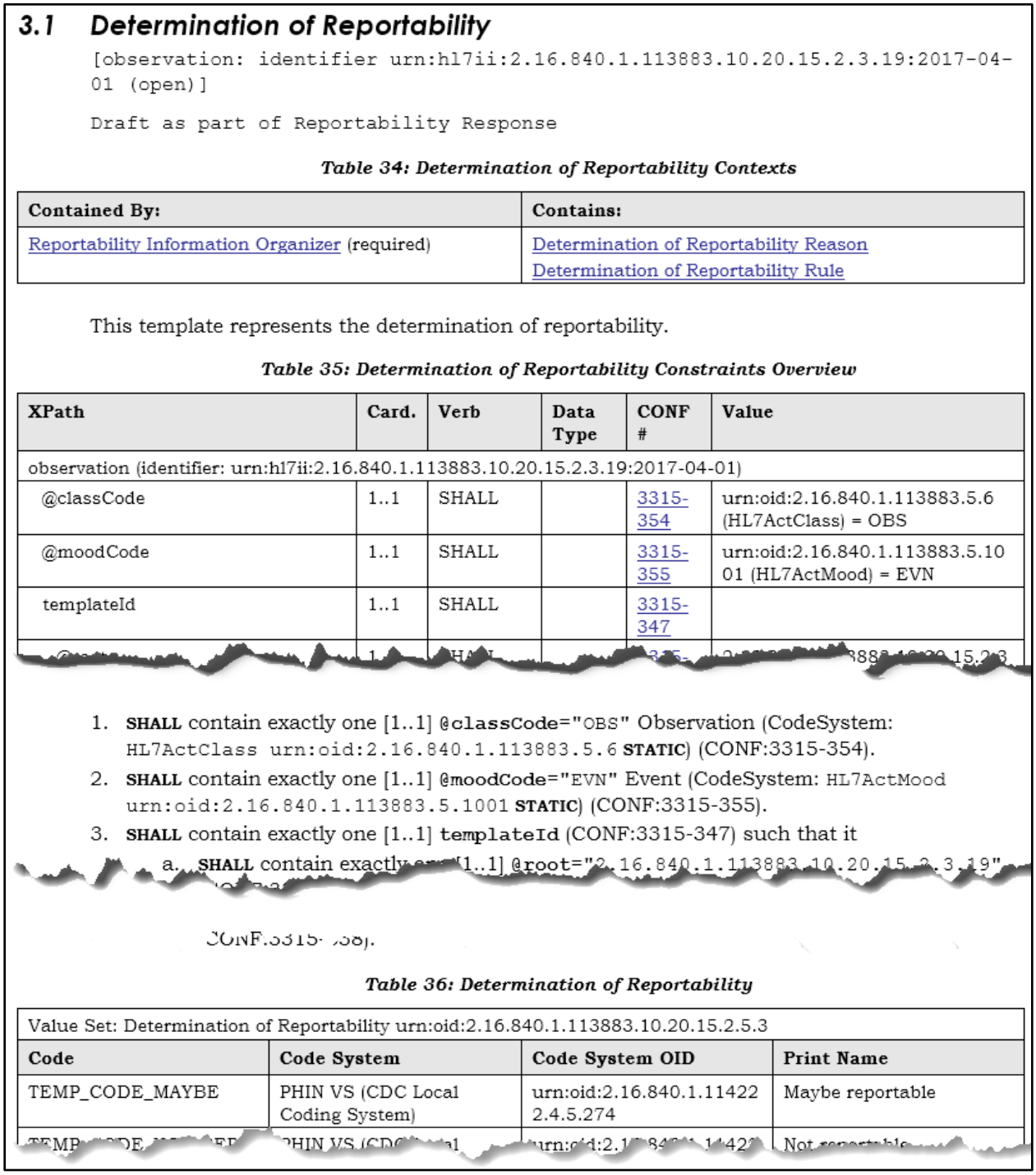
Conformance statements within this IG are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation. Each constraint is uniquely identified by a conformance number at or near the end of the constraint (e.g., CONF:86-7345). The set of digits in the conformance number before the hyphen identify which IG the template belongs to and the set of digits after the hyphen are unique to the owning IG. 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 context 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 constraint 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 5: 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"`

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.

4.1.2 Template Versioning

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

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

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

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 IG.

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 6: 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 7: 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 8: 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 9: 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 10: 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 11: 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 12: 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 13: 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 14: 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 15: Value Completely Unknown

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

Figure 16: 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 17: 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 18: 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 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 IG 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 19: 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 20: 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 IG, 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 21: 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 22: 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 23: 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 Participation 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. 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* (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:
    - Reportability Response Subject Section
        - Subject text
    - Reportability Response Summary Section
        - Summary text
        - Narrative guidance and associated links
    - Electronic Initial Case Report Section
        - ***eICR Identifier***
- If the eICR document was not processed and has errors then only the Electronic Initial Case Report Section will have a narrative text element that contains data from the following templates:
    - Electronic Initial Case Report Section
        - ***eICR Identifier*** (if available)
        - ***eICR Processing Status Reason***(s)

Possible ***eICR Processing Status Reason*** values include brief explanations of errors and warnings:

- eICR was not processed due to an error of: fatal problem with the eICR that was received
- eICR was not processed due to an error of: an ongoing server problem
- eICR was not processed due to an error of: significant content or format issues
- eICR was processed with a severe warning of: invalid eICR identifier
- eICR was processed with a severe warning of: required data not found
- eICR was processed with the warning of: content or format issues
- eICR was processed with the warning of: inactive RCTC code (indicates that the eICR contains a trigger code that is no longer active in the RCTC)
- eICR was processed with the warning of: outdated RCTC version (indicates that the version of the RCTC that was used to trigger the eICR is outdated {not the current version expected}. The expected RCTC version will be provided in the Expected RCTC Version data element.)

5.3 CDA Narrative Creation: Creator Responsibilities

The creator 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 based upon jurisdiction specific reporting requirements).

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

- An indication of a reportable condition or of no reportable conditions

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

- For a given eICR, the reportability determination for each possible condition identified
    - For each condition that was determined to be reportable to a given Responsible Agency (may be based on rules from a Rules Authoring Agency surrogate):
        - The name of the condition
        - The name of the Responsible Agency(ies) in which the condition was determined to be reportable (if available, the contact information for the Responsible Agency(ies) will be included in the external resources that follow 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 Responsible Agency(ies) for any follow-up (if available, the contact information for the Responsible agency(ies) will be included in the external resources that follow the narrative summary)
        - The data that are needed to determine reportability
        - Guidance for the provider or reporter about how to provide the missing data (e.g., by direct follow-up with the relevant public health agency, as part of a supplemental data request, or by manually initiating an eICR with an explanation that includes the missing data)."
    - For each condition that is determined to be not reportable for a specific PHA as determined by decision support:
        - The name of the condition
        - The name of the Responsible Agency(ies) in which the condition was determined to be not reportable
- 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) (if available, the contact information for the Responsible Agency(ies) will be included in the external resources that follow the narrative summary).

The ***External Resources*** (text and links) should follow this narrative summary in the Reportability Response and can be as important as the ***Reportability Response Summary*** narrative to be presented to *Providers* and *Reporters*. This text and links when available will have been entered by PHA representatives, in association with specific conditions, but PHAs that receive the Reportability Response may also want to see all of the guidance that has been provided.

Further information about expected content and formatting of the Reportability Response Subject and Summary narrative can be found in Volume 3 - Creator 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* as well as Public Health Agencies

5.4 CDA Narrative Rendering: Receiver Responsibilities

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 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 24: Hierarchy of CDA Templates in the Reportability Response

6.2 Identified Data Requirements

The table below contains an alphabetized list of data elements and select values for this standard identified by eCR stakeholders.[16]

Data Elements and Select Values	Description	Data Source[17]	For visualization?
Date and time of eICR Receipt	The date and time of eICR receipt by the entity that is generating the Reportability Response (to assist with troubleshooting and establish the elapsed time between the EHR sending the eICR and the creation of the Reportability Response)	Receiving system	In eICR Section/text, if eICR is not processed (error)
Determination of Reportability Reason	A reason indicating the reason for the reportability status	PHDS	Visualized when determination of reportability value = RRVS2 (May be reportable)
Determination of Reportability Rule	A rule that was involved in the determination of the reportability status	PHDS	No
Determination of Reportability Value	For each possible condition identified in the eICR and the relevant PHA(s), this code indicates the determination of whether the condition is reportable to public health. Generally, this is expected to be Reportable, Not reportable, or May be reportable (a determination can not be made without additional information), but at times may only indicate that no reporting rule was met in the decision support service.	PHDS	No
eICR CDA Document ID*	At a minimum, each Reportability Response should contain the unique document ID associated with the eICR that initiated its generation	eICR	Yes

[16] Input on Reportability Response data included a series of sessions, directed interviews, and nationwide presentations. Groups included were clinicians and clinical care representative organizations, individual Public Health Agencies, epidemiologists, State Health Officers, as well as the Council of State and Territorial Epidemiologists.

[17] Identifies the source of the data needed for this data element to populate the Reportability Response document. (eICR = from eICR associated with the Reportability Response, PHDS = Public Health Decision Support system, Receiving system = from an integration engine or validation tool output, RR constructor = will be an element populated using existing templates and other data from PHDS)

Data Elements and Select Values	Description	Data Source[17]	For visualization?
eICR CDA Document SetID	"set ID" could be used to associate eICRs and potentially other data from the EHR that are about the same patient and the same encounter The SetID and Document Version number must be used together for this purpose.	eICR	No
eICR CDA Document Version Number	Used in conjunction with eICR Set Id to manage document replacements, all documents in a chain of replacements have the same eICR Set Id and are distinguished by an incrementing integer value eICR Version Number.	eICR	No
eICR Encompassing Encounter ID	The encompassing encounter ID from the eICR that generated the Reportability Response	eICR	No
eICR Processing Status	The status of eICR processing, including an acknowledgement of successful processing or any known errors or warnings encountered during eICR processing	Receiving system	No
eICR Processing Status Reason	If the incoming eICR was not successfully processed for reportability determination by public health, this will contain the reason it was not processed."	Receiving system	Yes
eICR Validation Output (text output)	If the eICR could not be processed and resulted in an error, text output from validation describing the error(s) may be provided in this field	Receiving system	No
eICR Validation Output (link to output file)	If the eICR could not be processed and resulted in an error, a link to an output file from validation describing the error(s) may be provided in this field	Receiving system	No
Expected RCTC Version	Will be populated with the version of the RCTC that was expected by public health decision support. The EHR System Administrator should update to this version of the RCTC as soon as possible.	PHDS	No
External Resource Description	Brief description for “providers” or “reporters” that guides or directs them to additional information on the specific conditions deemed reportable by the PHA system (or its intermediary).	PHDS	Yes

Data Elements and Select Values	Description	Data Source[17]	For visualization?
External Resource Category	Type/category of an associated external resource. The possible categories in their intended order of presentation are: • Outbreak- or Cluster related • Additional reporting needs • Additional detection and/or laboratory testing needs • Treatment and/or prevention • PHA contact info • Additional resources	PHDS	No
External Resource Link	A Uniform Resource Identifier (URI) used to link to external sources of additional information or systems which will be used by *Providers* / *Reporters* to access information or take action on the specific conditions deemed reportable by the PHA	PHDS	Yes
External Resource Priority	Priority given to an associated external resource. Possible priorities include: • Immediate action required • Action required • Immediate action requested • Action requested • Information only	PHDS	Yes
Facility Address	The facility address received in the eICR	eICR	Yes
Facility Fax	The facility fax received in the eICR	eICR	Yes
Facility ID Number	The facility ID number received in the eICR	eICR	Yes
Facility Name	The facility name received in the eICR	eICR	Yes
Facility Phone	The facility phone received in the eICR	eICR	Yes
Facility Type	The facility type received in the eICR	eICR	Yes
Inactive RCTC Code	Code, codeSystem, valueSet, valueSetVersion of a code that exists within the eICR but has been labeled as inactive in the current RCTC	Code from eICR but identified as inactive by PHDS	No
Initial Case Report Manual Initiation Reason	Reason for manual initiation of the eICR	eICR	No
Filename of eICR	The filename of the eICR (to assist with troubleshooting in the event that the eICR cannot be parsed)	eICR file	Yes, for eICR with errors

Data Elements and Select Values	Description	Data Source[17]	For visualization?
Location Relevance	This code indicates whether the eICR was reportable to an identified responsible PHA because the patient's home address is located in that PHA's jurisdiction, the provider's facility address is located in that PHA's jurisdiction, or both.	PHDS	Yes
Manually Initiated eICR	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.	eICR	No
Outdated RCTC Version	If the version of the RCTC that was used to generate the eICR is outdated, the specific version outdated used. If this element is populated, EHR administrators can find the current version in the "Expected RCTC Version" element.	Version from eICR but identified as outdated by PHDS	No
Parent/ Guardian Email	If available, the parent or guardian email received in the eICR	eICR	Yes
Parent/ Guardian Name	The parent or guardian name received in the eICR	eICR	Yes
Parent/ Guardian Phone	The parent or guardian phone number received in the eICR	eICR	Yes
Patient Administrative Gender	The patient administrative gender received in the eICR	eICR	Yes
Patient Birth Date	The patient birth date received in the eICR	eICR	Yes
Patient Email	The patient email received in the eICR	eICR	Yes
Patient Ethnicity	The patient ethnicity received in the eICR	eICR	Yes
Patient ID Number	The patient ID number received in the eICR	eICR	Yes
Patient Name	The patient name received in the eICR	eICR	Yes
Patient Phone	The patient phone number received in the eICR	eICR	Yes
Patient Preferred Language	The patient's preferred language received in the eICR	eICR	Yes
Patient Race	The patient race received in the eICR	eICR	Yes
Patient Street Address	The patient address received in the eICR	eICR	Yes
Provider Address	The provider address received in the eICR	eICR	Yes
Provider Email	The provider email received in the eICR	eICR	Yes
Provider Fax	The provider fax received in the eICR	eICR	Yes

Data Elements and Select Values	Description	Data Source[17]	For visualization?
Provider ID	The provider ID received in the eICR	eICR	Yes
Provider Name	The provider name received in the eICR	eICR	Yes
Provider Phone	The provider phone number received in the eICR	eICR	Yes
Provider Facility/Office Name	The provider facility received in the eICR	eICR	Yes
Relevant Reportable Condition Name	The name of a reportable condition relevant to information included in the eICR.	PHDS	Yes
Relevant Reportable Condition Value	A code for a reportable condition relevant to the information included in the eICR	PHDS	No
Reportability Response CDA Document ID	Each Reportability Response document contains a unique ID. The Reportability Response CDA Document ID is different from the eICR CDA Document ID. The eICR CDA Document ID is also contained in the Reportability Response and used to link to the associated eICR.	RR Constructor	No
Reportability Response Priority	A value indicating the overall priority of the Reportability Response, derived from the highest priority level of the external resources contained in the coded section	RR Constructor	No
Reportability Response Subject	A succinct, human-readable narrative text that can be used as a subject header in a message queue, much like an email subject	PHDS and RR Constructor	Yes
Reportability Response Summary	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)	PHDS and RR Constructor	Yes
Reporting Timeframe	For a given condition , the mandated timeframe in which the condition should be reported to the PHA	PHDS	Yes
Responsible Agency Address Information	The physical address of the PHA to which reporting is legally required	PHDS	No
Responsible Agency Contact Information	Contact information such as telephone, fax, email, URL for the PHA to which reporting is legally required	PHDS	No
Responsible Agency Description	The description of the PHA to which reporting is legally required	PHDS	No

Data Elements and Select Values	Description	Data Source[17]	For visualization?
Responsible Agency Identifier	An identifier indicating the PHA to which reporting is legally required	PHDS	No
Responsible Agency Name	The name of the PHA to which reporting is legally required	PHDS	Yes
Routing Entity Address Information	The physical address of the PHA or other organization identified by the PHA (such as an HIE) to which the eICR (if deemed reportable) and/or the Reportability Response will be provided immediately following the creation of the Reportability Response.	PHDS	No
Routing Entity Contact Information	Contact information such as telephone, fax, email, URL for the PHA or other organization identified by the PHA (such as an HIE) to which the eICR (if deemed reportable) and/or the Reportability Response will be provided immediately following the creation of the Reportability Response.	PHDS	No
Routing Entity Description	The description of the PHA or other organization identified by the PHA (such as an HIE) to which the eICR (if deemed reportable) and/or the Reportability Response will be provided immediately following the creation of the Reportability Response. This entity may just be acting to route the eICR and Reportability Response on their way to a Responsible Agency.	PHDS	No
Routing Entity Identifier	An identifier indicating the PHA or other identified organization (such as an HIE) to which the eICR (if deemed reportable) and/or Reportability Response will be provided immediately following the creation of the Reportability Response.	PHDS	No
Routing Entity Name	The name of the PHA or other organization identified by the PHA (such as an HIE) to which the eICR and/or the Reportability Response may be provided immediately following the creation of the Reportability Response.	PHDS	Yes
Rules Authoring Agency Address Information	The physical address of the PHA whose rules are being executed in decision support to determine reportability. This may be a State or Local PHA.	PHDS	No
Rules Authoring Agency Contact Information	Contact information such as telephone, fax, email, URL for the PHA whose rules are being executed in decision support to determine reportability. This may be a State or Local PHA.	PHDS	No
Rules Authoring Agency Description	The description of the PHA whose rules are being executed in decision support to determine reportability. This may be a State or Local PHA.	PHDS	No
Rules Authoring Agency Identifier	An identifier indicating the PHA whose rules are being executed in decision support to determine reportability. This may be a State or Local PHA.	PHDS	No

Data Elements and Select Values	Description	Data Source[17]	For visualization?
Rules Authoring Agency Name	The name of the PHA whose rules are being executed in decision support to determine reportability. This may be a State or Local PHA.	PHDS	No

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 Elements and Select Values	CDA Section	CDA Mapping	CDA Data Type
Date and time of eICR Receipt	Electronic Initial Case Report Section	Received eICR Information/eICR External Document Reference/effectiveTime	TS
Determination of Reportability Reason	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Determination of Reportability/Determination of Reportability Reason/value	ANY
Determination of Reportability Rule	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Determination of Reportability/Determination of Reportability Rule/value	ANY
Determination of Reportability Value	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Determination of Reportability/value	CD
eICR CDA Document ID	Electronic Initial Case Report Section	Received eICR Information/eICR External Document Reference/id	II
eICR CDA Document Set ID	Electronic Initial Case Report Section	Received eICR Information/eICR External Document Reference/setId	II
eICR CDA Document Version Number	Electronic Initial Case Report Section	Received eICR Information/eICR External Document Reference/versionNumber	INT
eICR Encompassing Encounter ID	Header	ClinicalDocument/componentOf/encompassingEncounter/id	II
eICR Processing Status	Electronic Initial Case Report Section	eICR Processing Status/code	CD

Data Elements and Select Values	CDA Section	CDA Mapping	CDA Data Type
eICR Processing Status Reason	Electronic Initial Case Report Section	eICR Processing Status/eICR Processing StatusReason/value	CD
eICR Validation Output (text output)	Electronic Initial Case Report Section	eICR Processing Status/eICR Validation Output/value	ED
eICR Validation Output (link to output file)	Electronic Initial Case Report Section	eICR Processing Status/eICR Validation Output/value/reference[http:][https:]	TEL
Expected RCTC Version	Electronic Initial Case Report Section	eICR Processing Status/eICR Processing Status Reason/eICR Processing Status Reason Detail[code="RRVS33"]/value	ANY
External Resource Category	Reportability Response Summary Section	../External Resources/code	CD
External Resource Description	Reportability Response Summary Section	../External Resources/External Reference/code/originalText	ST
External Resource Link	Reportability Response Summary Section	../External Resources/External Reference/code/text/reference[http:][https:]	TEL
External Resource Priority	Reportability Response Summary 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[fax:]	TEL
Facility Phone	Header	ClinicalDocument/componentOf/encompassingEncounter/location/healthCareFacility/serviceProviderOrganization/telecom[tel:]	TEL

Data Elements and Select Values	CDA Section	CDA Mapping	CDA Data Type
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	eICR Processing Status Detail[code="RRVS32”]/value	ANY
Location Relevance	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/code	CD
Manually Initiated eICR	Electronic Initial Case Report Section	Manually Initiated eICR/code="PHC1464"]	CD
Outdated RCTC Version	Electronic Initial Case Report Section	eICR Processing Status Reason Detail[code="RRVS31"]/value	ANY
Parent/ Guardian Email	Header	Clinical Document/record target/patientRole/patient/guardian/telecom[mailto:]	TEL
Parent/ Guardian Name	Header	Clinical Document/record target/patientRole/patient/guardian/guradianPerson/name	PN
Parent/ Guardian Phone	Header	Clinical Document/record target/patientRole/patient/guardian/telecom[tel:]	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[mailto:]	TEL
Patient Ethnicity	Header	ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode + ClinicalDocument/recordTarget/patientRole/patient/sdtc: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:]	TEL

Data Elements and Select Values	CDA Section	CDA Mapping	CDA Data Type
Patient Preferred Language	Header	ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/languageCode	CD
Patient Race	Header	ClinicalDocument/recordTarget/patientRole/patient/raceCode + ClinicalDocument/recordTarget/patientRole/patient/sdtc:raceCode	CD
Patient Street Address	Header	ClinicalDocument/recordTarget/patientRole/addr	AD
Provider Address	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/representedOrganization/addr + ClinicalDocument/informationRecipient[typeCode="PRCP"]/intendedRecipient/receivedOrganization/addr	AD
Provider Email	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[mailto:] + ClinicalDocument/informationRecipient[typeCode="PRCP"]/intendedRecipient/telecom[mailto:]	TEL
Provider Facility/Office Name	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/representedOrganization/name + ClinicalDocument/informationRecipient/intendedRecipient[typeCode="PRCP"]/receivedOrganization/name	ON
Provider Fax	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[fax:] + ClinicalDocument/informationRecipient/intendedRecipient[typeCode="PRCP"]/telecom[fax:]	TEL
Provider ID	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/id + ClinicalDocument/informationRecipient[typeCode="PRCP"]/intendedRecipient/id	II
Provider Name	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/assignedPerson/name + ClinicalDocument/informationRecipient[typeCode="PRCP"]/intendedRecipient/informationRecipient/name	PN
Provider Phone	Header	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/telecom/[tel:] + ClinicalDocument/informationRecipient[typeCode="PRCP"]/intendedRecipient/telecom[tel:]	TEL
Relevant Reportable Condition Name	Reportability Response Summary Section	Relevant Reportable Condition Observation/value/@displayName	

Data Elements and Select Values	CDA Section	CDA Mapping	CDA Data Type
Relevant Reportable Condition Value	Reportability Response Summary Section	Relevant Reportable Condition Observation/value/@code	CD
Reportability Response Priority	Reportability Response Summary Section	Reportability Response Priority/value	CD
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 Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Reporting Timeframe/value	PQ
Responsible Agency Address Information	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/addr	ED
Responsible Agency Contact Information	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/telecom	TEL
Responsible Agency Description	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/playingEntity/desc	ED
Responsible Agency Identifier	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/id	II
Responsible Agency Name	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Responsible Agency/participantRole/playingEntity/name	PN

Data Elements and Select Values	CDA Section	CDA Mapping	CDA Data Type
Routing Entity Address Information	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/addr	AD
Routing Entity Contact Information	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/telecom	TEL
Routing Entity Description	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/playingEntity/desc	ED
Routing Entity Identifier	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/playingEntity/id	II
Routing Entity Name	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Routing Entity/participantRole/playingEntity/name	PN
Rules Authoring Agency Address Information	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Rules Authoring Agency/participantRole/addr	AD
Rules Authoring Agency Contact Information	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Rules Authoring Agency/participantRole/telecom	TEL
Rules Authoring Agency Description	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Rules Authoring Agency/participantRole/playingEntity/desc	ED
Rules Authoring Agency Identifier	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Rules Authoring Agency/participantRole/id	II
Rules Authoring Agency Name	Reportability Response Summary Section	Reportability Response Coded Information Organizer/Relevant Reportable Condition Observation/Reportability Information Organizer/Rules Authoring Agency/participantRole/playingEntity/name	PN

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 Standards 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 IG.
- 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.

