OneHealthPort HIE

Implementation Guide

Consolidated Clinical Documentation Architecture (C-CDA) Documents for Clinical Data Repository (CDR)

Revised: January 2023 Version 2.5

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1. DOCUMENT CHANGE HISTORY

DOCUMENT NAME: OHP-HIE Implementation Guide – C-CDA Documents			
Version	**Issue Date**	**Modified By**	**Comments/Reason**
1.0	February, 2016	Rhonda May	First draft of Implementation Guide for C-CDA Documents
1.1	February 17, 2016	Rhonda May	Clarification of data confidentiality requirements, update web link, correct typographical errors, add mapping table, add error handling section, add section for C-CDA correction.
1.2	February 22, 2016	Rhonda May	Updated Mapping Table
1.3	March 21, 2016	Rhonda May	Added information about mapping table information available on the OHP HIE website
1.4	April 2016	Rhonda May	Update name element sequence information
1.5	May 2016	Rhonda May	Add specific reference to the version of HL7 C-CDA implementation guide being used for C-CDA processing at the HIE. Update name element sequence information with reference to the implementation guide
1.6	August 2016	Rhonda May	Document enhancements, add/update specificity on data requirements and constraints, add supported XDS.b ITI protocols
1.7	October 2016	Rhonda May, Kelly Llewellyn and Sue Merk	Revised C-CDA requirements and data submission methods. Added information on Direct messaging.
1.8	October 2016	Rhonda May	Edits, clarifications and corrections, Direct error messaging
1.9	January 2017	Sue Merk	Edits and updates
2.0	July 2017	Rhonda May	Insert Best Practices and add edits and updates
2.1	September 2017	Rhonda May	Patient matching edits and updates
2.2	January 2018	Rhonda May	Sponsor changes, minor edits and updates
2.3	January 2019	Rhonda May	Updated for additional IHE transaction types supported and common workflow for querying the CDR
2.4	November 2019	Kelly Llewellyn	Removed reference to online validation testing. Website testing tool was retired in November 2019.
2.5	January 2023	Kelly Llewellyn	Removed reference to AS2 connectivity option. This connectivity was discontinued in December 2022. Removed information regarding electronic query options to the CDR.

2. INTRODUCTION

2.1 Overview

OneHealthPort offers Clinical Data Repository (CDR) services to organizations that are interested in collecting clinical information for a specific or “sponsored” population of patients. Current organizations sponsoring lives (Sponsors) and the patient lives being sponsored in the CDR are listed below. The CDR aggregates clinical data providing a patient-centric, longitudinal medical record inclusive of clinical records supplied by all contributing providers.

2.2 Clinical Data Repository Sponsors

Washington State Health Care Authority - Apple Health Program including Fully Integrated Managed Care (Managed Medicaid population)

2.3 Scope

This implementation guide, unique to the **OneHealthPort CDR**, provides information for:

- C-CDA validation testing for format conformance with national standards
- Identifying patient lives for C-CDA data submissions
- Patient matching with the CDR
- C-CDA data submission options
- C-CDA confidentiality coding

The implementation guide is intended to **augment** the HL7 national standard implementation guide specifically for the operationalization of C-CDA document exchange on the OneHealthPort HIE as well as the IHE protocols for document sharing. OneHealthPort is using the **HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1** which is available on the HL7 website.

2.4 General Assumptions

- Organizations participating in the sponsored CDR initiatives are contracted with the OneHealthPort HIE.
- The OneHealthPort HIE provides the supporting technical infrastructure for C-CDA data submissions to the CDR.
- HIE participating organizations will successfully "pre-validate" C-CDA documents with validation testing tools provided or accepted by OneHealthPort, prior to submission to the HIE. (See section 3 below.)
- Organizations and vendors will develop and manage processes for identifying patients for C-CDA data submissions, error message handling and automation of submissions.
- Confidentiality of clinical information sent in C-CDA documents is the responsibility of the submitting organization, using the HL7 Basic Confidentiality Kind value set where N = Normal, R = Restricted, and V = Very Restricted.

2.5 Terms and Acronyms

Term or Acronym	Description or Additional Detail
CCD	Continuity of Care Document
C-CDA	Consolidated Clinical Data Architecture – a framework for electronic exchange of clinical documents
CDR	Clinical Data Repository – an OHP service providing a hosted database of specifically defined patient lives that are sponsored by organizations such as the State of Washington Health Care Authority (HCA). Data is segmented by sponsoring organization.
EHR	Electronic Health Record
HIE	Health Information Exchange
HL7	Health Level 7 – a healthcare standards setting organization having a defined set of international standards for transfer of clinical and administrative data between software applications used by various healthcare practitioners.
IHE	Integrating the Healthcare Enterprise - a non-profit organization based in the US state of Illinois. It sponsors an initiative by the healthcare industry to improve the way computer systems share information.
ITI-41	The IHE XDS.b standard message wrapper (ITI-41) for providing and registering documents in a repository
NIST	National Institute of Standards and Technology
SSN	Social Security Number
XDS.b	IHE Cross Enterprise Document Sharing interoperability profile

3. C-CDA DOCUMENT VALIDATION

3.1 Overview

OneHealthPort HIE participating organizations exchanging C-CDA documents are required to perform validation testing to confirm messages conform to the HL7 CDA_R2 standard. This validation is the **baseline requirement** for a file to successfully ingest and parse in the CDR. In addition to meeting formatting requirements all C-CDA xml files must be UTF-8 encoded for processing by the CDR.

3.2 C-CDA Document Automated Validation

C-CDA files submitted to the CDR in both the test and production environments are sent through an automated inline schema validation tool to ensure the file conforms with the national HL7 CDA_R2 standard before being processed by the CDR. Files that fail the validation are not processed, and schema validation error information is sent back to the submitting organization in the error response messages.

4. PATIENT IDENTIFICATION FOR C-CDA DATA SUBMISSION

4.1 Overview

The OneHealthPort CDR accepts clinical data submissions for sponsored patient lives and does not accept C-CDA data submissions for patients not specified by a data Sponsor. Therefore, organizations participating in sponsored CDR initiatives will need to work with their EHR vendor to identify or flag patients for C-CDA data submissions based on identification information provided by the data Sponsor and send data only for those patients.

4.2 Sponsored Patient Identification Information

CDR Sponsors' information is posted on the OneHealthPort CDR website. Sponsors provide patient identification information to the CDR through eligibility uploads. Sponsors also identify specific information about the health plans under which sponsored patients are covered. Provider organizations contracted with and caring for patients covered under the health plan products on the sponsor's list must submit C-CDAs for these patients after an encounter. A Health Plan Product File is available at the OneHealthPort website on the Prepare the C-CDA page in the **CCDA Implementation Guide** section of the page.

5. PATIENT MATCHING AT THE CDR

5.1 Overview

C-CDAs submitted to the CDR are matched through a process of internal queries using the following:

- An EXACT MATCH on patient last and first name and date of birth. If data from the C-CDA is not an exact match with a known patient in the CDR, or if there is a match with more than one patient, the message is rejected and returned with a no patient match error.

5.2 Patient Matching Process

The patient matching process supported by the CDR is based on what is available from the sponsor compared to what the submitter has obtained from the patient.

5.2.1 Patient Demographic Matching

Patient demographic matching at the CDR uses specific fields contained in the C-CDA. Organizations are encouraged to verify that patient demographic information collected and stored in the EHR at the time a patient presents for care is accurate and matches the Sponsors eligibility information. The demographic fields in the C-CDA used for patient matching are:

- First Name (required)

- Last Name (required)
- Date of Birth (required)

When a C-CDA is received the CDR will launch an internal query to find a patient match based on patient demographic data.

- If an exact match is found, the patient global identifier and CDR OID will be inserted into the C-CDA and processed by the CDR.
- If an exact match is not found, or if multiple matches are found, then the CDR will send back an error to the submitting organization and the organization will need to investigate the reason for no patient match.

6. C-CDA DATA SUBMISSION OPTIONS

6.1 Overview

C-CDA submissions are required following a patient encounter. Organizations are encouraged to submit C-CDAs within a reasonable time period following the patient visit, when the C-CDA is deemed complete in the EHR and ready for submission.

OneHealthPort supports two different C-CDA data submission pathways to the CDR. The options below can be used to support the submission of validated C-CDA messages using existing functionality available in electronic health record (EHR) systems. Organizations can work with their vendors to use the option that best supports their system data submission capabilities and operational processes.

6.1.1 ITI-41 XDS.b Web Services Transaction Using Certificate-Based Exchange

Organizations will be required to provide certificates to establish secure connectivity to the OneHealthPort HIE as well as a URL that will be available for the HIE to send message disposition notifications (MDNs) and error processing messages from the CDR back to the organization. Certificate requirements and endpoint URLs are provided in the Web Services Implementation Guide. (See the Web Services Implementation Guide for full details)

6.1.2 Direct Message

Organizations choosing this data submission option will be required to send the C-CDA in a validated xml format to the CDR's Direct Mail address. (See the Direct Message Implementation Guide for full details)

7. CORRECTION OF C-CDA DATA SUBMISSIONS

7.1 Overview

Organizations may need to periodically update, append or replace previously submitted C-CDAs.

7.2 C-CDA Submission Correction and Updates

The HL7 C-CDA standard provides for correction and updates through relatedDocument functionality. Organizations sending appended or replacement C-CDA documents must include an additional section in the C-CDA message header. The location in the header for the relatedDocument information is after the documentationOf section, and is shown below:

relatedDocument	0..*	MAY	1098-29893	
@typeCode	1..1	SHALL	1098-31889	2.16.840.1.113883.11.20.9.62 (Related Document (append/replace))
parentDocument	1..1	SHALL	1098-29894	

Source: CDAR2_IG_CCDA_CLINNOTES_R2_D1_2014NOV_V2_Templates_and_Supporting_Material

Organizations submitting replacement or appended C-CDAs must take the following course of action:

1. Identify the unique document identifier sent in the originally submitted CCD <id> root and extension attributes and send that information relative to the parentDocument as shown below
2. The document identifier must be used as the parentDocument id element. An example of the relatedDocument section is show below:

```
<relatedDocument typeCode="RPLC">
<parentDocument>
<id root="aefe4f6a-d6e1-46ef-8c40-790998f7bee6" />
<code code="34133-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="SUMMARIZATION OF EPISODE NOTE"/>
```

8. C-CDA CONFIDENTIALITY CODES

8.1 Overview

Data confidentiality codes assigned to clinical documents **drive all access control** to individual patient records in the Clinical Data Repository. It is the responsibility of the submitting organization to code the content in the C-CDA based upon the type of content in an encounter, or the patient request for data to be treated with sensitivity.

8.2 Data Confidentiality Codes

Currently, the entire C-CDA has only one **confidentiality code** that **should be based on the most confidential element in the document**. In the future, confidentiality coding will be accepted at the element level. Further information regarding the HL7 standard discussing confidentiality code assignment can be found by an internet search using the confidentiality code system object identifier 2.16.840.1.113883.5.25. The HL7 link is as follows: http://www.hl7.org/documentcenter/public_temp_2873DC00-1C23-BA17-0C63F6C676FED8DB/standards/vocabulary/vocabulary_tables/infrastructure/vocabulary/vs_Confidentiality.html

Electronic Health Record (EHR) systems must provide the means for the practitioner to identify the correct confidentiality code for information included in the C-CDA. "Normal" (N) may be the system default for data confidentiality. The EHR system must provide functionality to adjust the confidentiality code to match the information in the record.

The State of Washington Health Care Authority has developed a reference guide for Confidentiality code assignment based on ICD-10 and CPT-4 Codes associated with the record. This guide can assist vendors and practices with examples for how to classify data.

Currently the C-CDA accommodates the HL7 Basic Confidentiality Kind. In the future the standard may add a "sensitivity" classification providing more discreet definition of particular data/information in a record. A table of the confidentiality codes and their definition is shown below:

Code	Description	Definition
N	Normal	Privacy metadata indicating that **the information is typical, non-stigmatizing health information, which presents typical risk of harm** if disclosed without authorization. Includes what HIPAA identifies as the minimum necessary protected health information (PHI) given a covered purpose of use (treatment, payment, or operations). Includes typical, non-stigmatizing health information disclosed in an application for health, workers compensation, disability, or life insurance.

R	Restricted	Privacy metadata indicating **highly sensitive, potentially stigmatizing information, which presents a high risk to the information subject if disclosed without authorization**. May be preempted by jurisdictional law, e.g., for public health reporting or emergency treatment. Includes information that is additionally protected such as sensitive conditions mental health, HIV, substance abuse, domestic violence, child abuse, genetic disease, and reproductive health; or sensitive demographic information such as a patient's standing as an employee or a celebrity. May be used to indicate proprietary or classified information that is not related to an individual, secret ingredient in a therapeutic substance, or the name of a manufacturer.
V	Very Restricted	Privacy metadata indicating that the **information is extremely sensitive and likely stigmatizing health information that presents a very high risk if disclosed** without authorization. This information must be kept in the highest confidence. Includes information about a victim of abuse, patient requested information sensitivity, and taboo subjects relating to health status that must be discussed with the patient by an attending provider before sharing with the patient. May also include information held under legal lock or attorney-client privilege

Source: http://hl7.org/fhir/v3/Confidentiality/index.html

9. C-CDA DOCUMENT RENDERING AND PARSING IN THE CDR

Overview

When a document successfully uploads in the CDR, the entire document will render. Currently, the components of the CDR that will parse with discrete data, if all appropriate formatting/coding is included in the submitted document, are as follows:

- Documents – a listing of all the documents in the system for a given patient
- Medications
- Vital Signs
- Immunizations
- Problems
- Allergies
- Procedures
- Results

Sample screen shots of a rendered document:

Continuity of Care Document (Transition of Care)

Created On: January 14, 2019

Patient: ONEHEALTH PORT
99 RANGER DR
OLYMPIA, WA, 98502
tel:(222)456-1235

MRN: J000020251

Birthdate: April 16, 1921

Sex: Male

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Allergies, Adverse Reactions, Alerts

Allergen	Type	Severity	Reaction	Last Updated	Verified	Status
strawberry	Allergy	Mild	Bradycardia	January 11, 2019	Y	Active
barium sulfate	Adverse Reaction	Severe	Cardiac Arrest	January 11, 2019	Y	Active

Medications

Active Medications

Medication	Dose	Units	Route	Sig	Start Date	Status
Glucophage 50	MCG		PO	After Dialysis	January 11, 2019	Active
Lipitor	40	MG	PO	Daily	January 11, 2019	Active

Problem List

Active Problems

Medical Problem	Onset Date	Status
Skin abnormalities		Active
IMO-PROB-79620		Active

Procedures

Procedure	Date	Status
Barium Swallow	January 11, 2019	completed

Relevant Diagnostic Tests and/or Laboratory Data

Laboratory Results

Test	Date/Time	Result	Interp.	Ref. Range	Result Comment
White Blood Count	January 11, 2019 7:36am	15.0 X10E3/ul	High	4.8-10.8	
Red Blood Count	January 11, 2019 7:36am	6.00 x10E6/uL		4.50-6.10	
Hemoglobin	January 11, 2019 7:36am	11.0 g/dL	Low	13.5-17.5	
Hematocrit	January 11, 2019 7:36am	40.0 %		40.0-52.0	
Mean Corpuscular Volume	January 11, 2019 7:36am	90 fL		80-99	
Mean Corpuscular Hemoglobin	January 11, 2019 7:36am	30 pg		27-33	
Mean Corpuscular Hemoglobin Concent	January 11, 2019 7:36am	35 g/dL		31-35	
Red Cell Distribution Width	January 11, 2019 7:36am	12.0 %		11.5-15.5	
Platelet Count	January 11, 2019 7:36am	200 x10E3/uL		130-400	
Mean Platelet Volume	January 11, 2019 7:36am	10.0 fL		8.9-12.4	
Granulocytes % (Auto)	January 11, 2019 7:36am	45.0 %			
Immature Granulocyte % (Auto)	January 11, 2019 7:36am	0.1 %		0.0-1.0	
Lymphocytes (%) (Auto)	January 11, 2019 7:36am	30.0 %		20.0-50.0	
Monocytes (%) (Auto)	January 11, 2019 7:36am	12.0 %	High	2.0-11.0	
Eosinophils (%) (Auto)	January 11, 2019 7:36am	7.0 %		0.0-7.0	
Basophils (%) (Auto)	January 11, 2019 7:36am	2.0 %		0.0-2.0	
Granulocytes # (Auto)	January 11, 2019 7:36am	5.00 x10E3/uL		1.40-6.50	
Immature Granulocyte # (Auto)	January 11, 2019 7:36am	0.02 x10E3/uL		0.00-0.03	
Lymphocytes # (Auto)	January 11, 2019 7:36am	3.00 x10E3/uL		1.20-3.40	
Monocytes # (Auto)	January 11, 2019 7:36am	0.80 X10E3/uL		0.00-0.90	
Eosinophils # (Auto)	January 11, 2019 7:36am	0.70 x10E3/uL		0.00-0.80	
Basophils # (Auto)	January 11, 2019 7:36am	0.20 x10E3/uL		0.00-0.20	

Advance Directives

Advance Directive	Response	Recorded Date/Time
Do you have an advance directive?	No	January 8, 2019 9:17am

Chief Complaint and Reason for Visit

Encounter	Admit Date	Chief Complaint	Reason for Visit
Discharged Inpatient	January 8, 2019 9:06am	TESTING OHP	IMO-PROB-79620 Skin abnormalities

Hospital Discharge Instructions

No known hospital discharge instructions.

Hospital Discharge Medications

Medication	Dose	Units	Route	Sig	Qty Days	Order Date	Status	Instructions
Glucophage 50	MCG		PO	After Dialysis		January 11, 2019	Active	
Lipitor	40	MG	PO	Daily		January 11, 2019	Active	

Encounters

Encounter	Facility	Location	Admit/Visit Date	Discharge/Departure Date	Attending Provider
Discharged Inpatient	Capital Medical Center	Intensive Care Unit	January 8, 2019 9:06am	January 14, 2019 8:00am	Abbott, Zachary

Encounter Diagnosis Onset Date
IMO-PROB-79620
Skin abnormalities

Functional Status

No known functional status.

Immunizations

Immunization Name	Date Given	Type
TB Skin test	January 11, 2019	Historical

Payers

Payer Name	Policy Type	Covered Party	Relationship	Subscriber
AARP UHC MEDICARE COMPLETE		ONEHEALTH PORT	Self	ONEHEALTH PORT
MOLINA HLTHY OPTIONS MCD		ONEHEALTH PORT	Self	ONEHEALTH PORT

System Assigned Code

Plan of Care

No Known Plan of Care Information

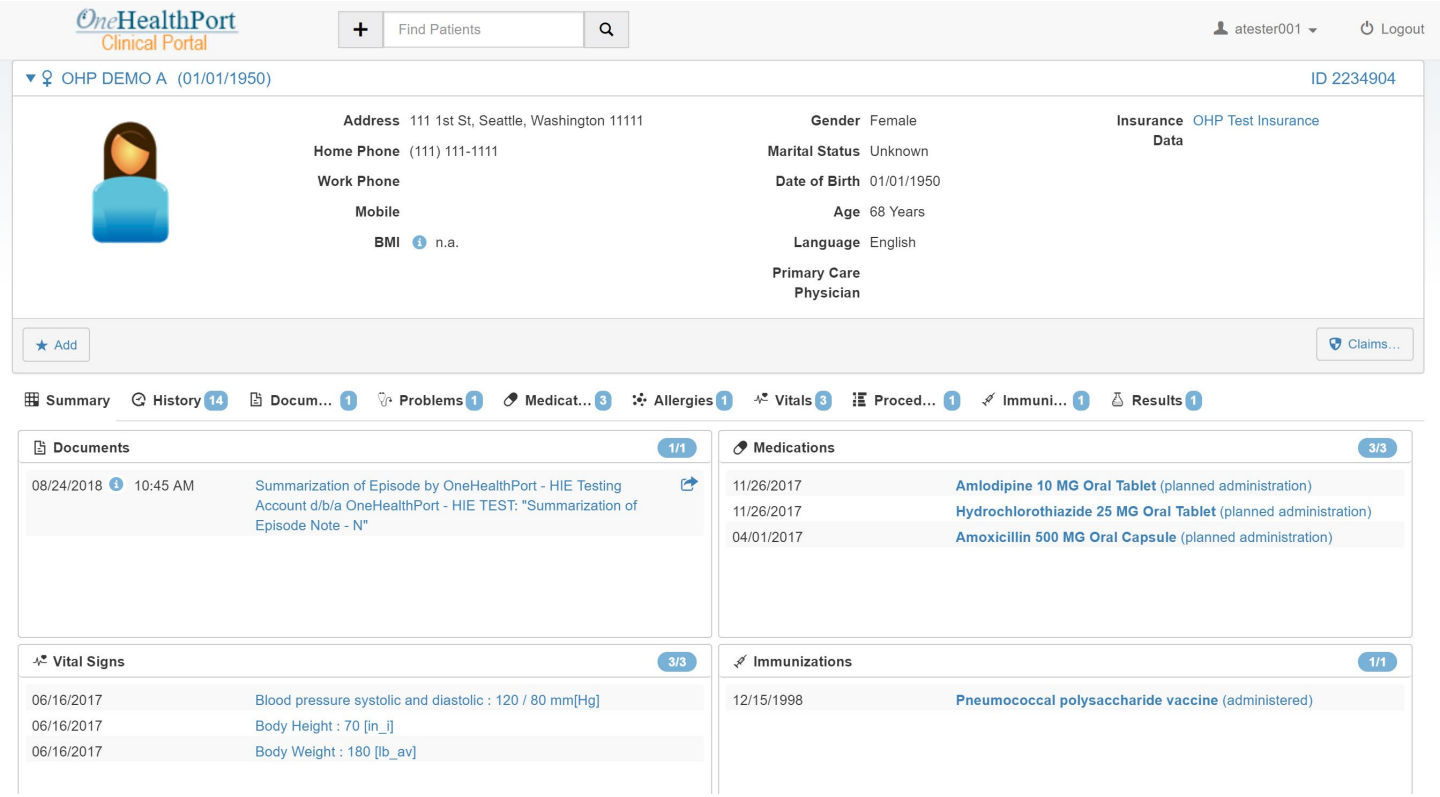
Social History

No known social history.

Vital Signs

Vital Reading	Result	Reference Range	Collection Date/Time
Height	5 ft 5 in		January 11, 2019 8:10am
Weight	52.394 kg		January 11, 2019 8:10am
Temperature	99 F	96.8 F-100.4 F	January 11, 2019 8:09am
Pulse	70 BPM	60-120	January 11, 2019 8:09am
Respiration	18 RPM	12-20	January 11, 2019 8:09am
Pulse Oximetry	99 %	90-100	January 11, 2019 8:09am
Blood Pressure Systolic	140	90-139	January 11, 2019 8:09am
Blood Pressure Diastolic	90	55-89	January 11, 2019 8:09am
Body Mass Index	19.2		January 11, 2019 8:10am

Sample screen shot of parsed data:



10. IHE DATA SUBMISSION PROTOCOLS SUPPORTED BY THE ONEHEALTHPORT HIE

10.1 Overview

The OneHealthPort HIE supports web service transactions using IHE protocols that can be leveraged and used for supporting information exchange activity with the CDR. For detailed information on the web services transactions see the Web Services Implementation Guide on the OneHealthPort website, Prepare the C-CDA page in the **Connecting for C-CDA Document Submission** section of the page.

10.2 Supported Submission Protocols

See the OneHealthPort Web Services Implementation Guide document for specific details on the web service transaction requirements. The web service transaction currently supported is the following:ITI-41NS Non-standard Provide and Register Document Set – used with customers wanting to do web service transaction processing but unable to match the specific ITI41 requirements for the Clinical Data Repository.

11. BEST PRACTICES FOR CCDA SUBMISSIONS

11.1 Overview

OneHealthPort is offering the following recommendations as best practices for organizations submitting C-CDA documents to the clinical repository. This section of the guide will be updated periodically with additional experience and as new information becomes known.

- Submit encounter-based CCD for the current visit/procedure being reported.

- If an initial historical submission is a system requirement, please limit it to 6 months of history. If possible, do not submit history on every encounter for a patient.
- If more than one submission is made on the same encounter, subsequent submissions should use the “Append” or “Replace” convention of the XDS.b standard so that the patient record does not end up with multiple near-identical entries for the same patient in the same day or a few days span. A single document for a single encounter is preferred.
- If a patient has more than one encounter in the same organization in the same day, a single CCD for all activities is preferred. Holding the encounter for results and final sign-off of the encounter is preferred over multiple reports in the same day.