



# **Florida Department of Health**

## **Bureau of Epidemiology**

### **Guide to Importing Data Into the National Healthcare Safety network: Bloodstream Infection Events**

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### Version Control

Version 1.0	11/29/2010	Original version
Version 1.1	12/22/20	Changed wording in sections 1, 1.1, 1.4, 4.8 and 5 for better clarification.  Removed the MDRO bullet from section 1.4.

# 1. Introduction

The purpose of this help document, developed by the Florida Department of Health (FDOH), is to assist facilities with creating the Clinical Document Architecture (CDA) files needed for importing the Primary Bloodstream Infection (BSI) numerator report into the National Healthcare Safety Network (NHSN). This document will use CDA to refer to an XML file that follows the CDA format which is the required file type and format for importing data into the NHSN system. CDA is a set of constraints on the HL7 Reference Informational Model (RIM) that are defined in the CDA Release 2 (CDA R2) Refined Message Information Model (RMIM) to further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements. NHSN is a web-based system maintained by the Centers for Disease Control (CDC) where facilities can report healthcare-associated infections (HAI) for quality improvement purposes or in compliance with Centers for Medicare and Medicaid (CMS) Hospital Inpatient Quality Reporting Program.

The directions in this document are taken from the CDC HL7 Implementation Guide for CDA Release 2 NHSN Healthcare Associated Infection (HAI) Reports, Release 5 (U.S. Realm). Summarization of the CDC HL7 Implementation Guide document will help direct the developer to the sections needed for the specific report being discussed in this document. The section and table numbers used within this document have been labeled and numbered as they are in the CDC [HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection \(HAI\) Reports, Release 5](#) so as to make the references between the two documents straightforward. An example of the [BSI-NUM Example](#) CDA file provided by the CDC will also assist in their development of the import file.

## 1.1 Audience

The target audience for this document is primarily developers of software systems who want to enable their system to report HAI data to the NHSN and secondarily, Infection Preventionists (IP) who will be working with their software system developers.

## 1.2 Schedule of Events

Each IP and software system development group will have to set up a schedule for when and how often data will be added to the NHSN system. Since data can be imported at any time, one facility may decide to import daily, while another facility may decide to only import weekly. When a schedule of events is determined, the IT group can assist in setting up a scheduled job that will create the CDA file so the assigned group can import the file into NHSN.

## 1.3 Other Help Locations

If you need additional details that are not available in this document, there are several help documents available for reference on the CDC website and the Florida Department of Health website. Below is a list of the other help locations and documents:

- For questions concerning this document, please contact June Leverette at [HAI\\_Program@doh.state.fl.us](mailto:HAI_Program@doh.state.fl.us).

- CDC Release 5 document: [HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection \(HAI\) Reports; Release 5](#).
- Example of a BSI XML file at [BSI Nun Example](#).
- The CDC NHSN website can be accessed at <http://www.cdc.gov/nhsn/index.html>.
- If the help documents do not provide the information you need, you can always contact NHSN by emailing [nhsn@cdc.gov](mailto:nhsn@cdc.gov) or thru their web site at <http://www.cdc.gov/nhsn/contact.html>.

## 1.4 Things to Note when Creating a CDA File

Below is a list of additional information that may be helpful in clarifying some questions when trying to create a CDA file.

- The CDA file is designed to only import the required fields on each report. Optional fields on the report forms are not included in the CDA file. A couple of exceptions where optional fields can be included in the CDA file are: patient first, last, and middle names, and contributed to death question.
- Before a CDA file can be created, the facility OID number must be known to the group that will create the import file. To see if the facility OID has been registered with NHSN review the section on OIDs in the “[FDOH Guide to Importing Data into NHSN: Initial Setup](#)” document located on the Florida Department of Health HAI website for instruction on registering with NHSN. The facility OID will be extended to create the unique numbering schemes needed to create the CDA files. The scheme of OID numbers will include the vendor or IT Group number.
- References to tables within this document are in the appendices of the CDC [HL7 Implementation Guide for CDA Release 2: HAI Reports Release 5](#) document.
- Numerator and Denominator reports are two separate reports and therefore two separate CDA files. A Numerator report is the individual file with the patient level data. The Denominator report is a summary file that provides patient days and central line days for a given location, month and year. These two reports stand on their own but both reports are required for calculating HAI rates.

## 2. Use of Implementation Guide

The implementation guide section contains information that is important in understanding this FDOH document. The information in this FDOH document comes directly from the CDC [HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection \(HAI\) Reports, Release 5](#) document which should be referenced if more information is needed.

### 2.1 (1.6.1 Keywords)

The following keywords in this document are to be interpreted as:

- **SHALL**: an absolute requirement, but allows for NULL values via an additional conformance statement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

## 2.2 (1.6.2 Constraints)

The CDA conformance statements are shown in figure 1 below with each constraint uniquely identified by an identifier at or near the end of the constraint (e.g., "CONF: 605"). Note that the identifiers are persistent not sequential.

**Figure 1 (Figure 1: Constraints format example)**

<p><b>Immunocompromised Observation</b></p> <p>[observation: templateId 2.16.840.1.113883.10.20.5.6.19]</p> <p>[description of the template]</p> <ol style="list-style-type: none"> <li>1. <b>SHALL</b> contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) <b>STATIC</b> (CONF:2348)</li> <li>2. <b>SHALL</b> contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) <b>STATIC</b> (CONF:2349)</li> <li>3. <b>SHALL</b> contain [1..1] code/@code="ASSERTION" Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) <b>STATIC</b> (CONF:2350)</li> <li>4. <b>SHALL</b> contain [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) <b>STATIC</b> (CONF:2351)</li> <li>5. <b>SHALL</b> contain [1..1] value/@code="370388006" Patient immunocompromized (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) <b>STATIC</b> (CONF:2352)</li> </ol>
---

The conformance verb keyword at the start of a constraint (**SHALL**, **SHOULD**, **MAY**, etc.) indicates business conformance and the cardinality indicator (0..1, 1..1, 1..\*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators may be interpreted as follows:

- 0..1 as zero to one present
- 1..1 as one and only one present
- 1..\* as one or more present
- 0..\* as zero to many present

## 2.3 (1.6.5 Succession Management)

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

electronic file) and the incremented version numbers identify subsequent versions of the document.

NHSN assigns each participating vendor a root Object Identifier (OID) and the vendor is responsible for controlling the structure of OIDs assigned under its root.

- To find out if your facility has already been assigned an OID you will need to log into the NHSN system. From the Navigation menu select the “Facility > Facility Info” and the OID should be displayed in the Object Identifier field.
- If your facility has not already been assigned an OID follow the directions in the [FDOH Guide to Importing Data into NHSN: Initial Setup](#) to receive an OID for the facility. Each OID owner such as a facility or vendor controls the structure of the OIDs it assigns under its root, and is responsible for ensuring that each identifier it issues is globally unique. A vendor must, for example, ensure that there is no duplication amongst the setIds issued by its various software installations. The example instance identifiers in this guide use the following plan for assigning instance identifiers:

**Table 1 (Table 79: Structure of Example OIDs)**

Usage	OID
a healthcare facility OID	2.16.840.1.113883.3.117.1.1.5.1.1
its patient IDs	2.16.840.1.113883.3.117.1.1.5.1.1.1
its non-patient IDs	2.16.840.1.113883.3.117.1.1.5.1.1.2
a vendor OID	2.16.840.1.113883.3.117.1.1.5.2.1
its first software installation	2.16.840.1.113883.3.117.1.1.5.2.1.1
its setIds	2.16.840.1.113883.3.117.1.1.5.2.1.1.1
its document IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.2
its encompassing encounter IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.3
its procedure IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.4

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

**Table 2 (Table 80: Values of Example Instance Identifiers Used in This Guide)**

Facility IDs and Facility-assigned OIDs		
Usage	OID	extension
a location in a facility	2.16.840.1.113883.3.117.1.1.5.1.1	9W
a patient ID	2.16.840.1.113883.3.117.1.1.5.1.1.1	123456
an author ID	2.16.840.1.113883.3.117.1.1.5.1.1.2	anAuthorID
a legal authenticator ID	2.16.840.1.113883.3.117.1.1.5.1.1.2	aLegalAuthenticatorID
Vendor IDs and Vendor-assigned OIDs		
Usage	OID	extension
a setId	2.16.840.1.113883.3.117.1.1.5.2.1.1.1	31
a document ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.2	20202201

an encompassingEncounter ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.3	31
a procedure ID	2.16.840.1.113883.3.117.1.1.5.2.1.1.4	92

## 2.4 (1.8 Supporting Tool)

IT groups checking the CDA file they have generated for errors in the file may find the use of the Schematron schemas helpful. Please refer to the HL7 Implementation Guide for CDA Release 2, Release 5 for the detail and location of the Schematron technology and for the location of the CDA Validator, which is available as an online application that can be used to validate the CDA document's conformance.

## 3. (3.1 Summary of TemplatedId Used Across Report Types)

Each CDA file that will be uploaded into the NSHN system must contain certain information. Below are the report-specific requirements for the Primary Bloodstream Infection (BSI) Report. These requirements specify the document-level templatedId value that identifies the report type, the preferred report title, and the sections required in that report type.

**Table 3 (Table 5: Sequence of Sections / Templates within Report Types)**

Italics indicate conditional requirements. All other items are required, except in the instance of an "or" that indicates a choice between sets of required items.

HAI Implementation Guide (2.16.840.1.113883.10.20.5.4.20)	
Document	Section and Clinical Statements Libraries
<b>Infection-type Reports</b>	
Bloodstream Infection Report ( <a href="#">...20.5.7</a> )	<p>Infection Risk Factors (BSI) Section (<a href="#">...20.5.5.1</a>)</p> <ul style="list-style-type: none"> <li>• Infection Risk Factors Observation(s) (<a href="#">...20.5.2.1.1.1</a>) and/or Infection Risk Factors Measurement Observation(s) (<a href="#">...20.5.2.1.1.2</a>) (dependent on location type)</li> </ul> <p>Infection Details (BSI) Section (<a href="#">...20.5.5.6</a>)</p> <ul style="list-style-type: none"> <li>• Infection-type Observation (<a href="#">...20.5.6.23</a>) <ul style="list-style-type: none"> <li>○ Criteria of Diagnosis Organizer (<a href="#">...20.5.6.11</a>) <ul style="list-style-type: none"> <li>▪ Criterion of Diagnosis Observation(s) (<a href="#">...20.5.6.10</a>)</li> </ul> </li> <li>○ Bloodstream Infection Evidence Type Observation (<a href="#">...20.5.6.4</a>)</li> </ul> </li> </ul> <p><i>(If patient died)</i></p> <ul style="list-style-type: none"> <li>▪ <i>Death Observation</i> (<a href="#">...20.5.6.12</a>) <ul style="list-style-type: none"> <li>○ <i>Infection Contributed to Death Observation</i> (<a href="#">...20.5.6.22</a>)</li> </ul> </li> </ul> <p>Findings Section (<a href="#">...20.5.5.15</a>)</p> <ul style="list-style-type: none"> <li>▪ <i>Pathogen Identified Observation (no pathogens identified)</i> (<a href="#">...20.5.2.5.1</a>)</li> </ul> <p><b>or</b></p> <ul style="list-style-type: none"> <li>▪ <i>Findings Organizer(s)</i> (<a href="#">...20.5.6.14</a>) <ul style="list-style-type: none"> <li>○ Pathogen Identified Observation (<a href="#">...20.5.2.5.1</a>)</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>○ Pathogen Ranking Observation (<a href="#">...20.5.2.5.1.1</a>)</li> <li>○ Drug-susceptibility Test Observation(s) (<a href="#">...20.5.2.5.1.2</a>)</li> </ul> <p><i>(and, conditionally)</i></p> <ul style="list-style-type: none"> <li>▪ MDRO Observation (<a href="#">...20.5.6.24</a>)</li> <li>▪ Significant Pathogens Observation (<a href="#">...20.5.6.41</a>)</li> <li>▪ CDAD Observation (<a href="#">...20.5.6.5</a>)</li> </ul>
--	--

## 4. (2 NHSN HAI Generic Constraints)

Section four briefly describes the CDA constraints common across all single-patient HAI report types.

The individual report-specific constraints are defined in the [report-specific constraints](#) above and the body of the CDF file is defined in this NHSN HAI Generic Constraints section and the [Generic Constraints](#) section below. If additional information is needed about the NHSN HAI generic constraints please refer to Section 2 of the HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 5 (US Realm).

### 4.1 (2.1 Healthcare Associated Infection Report)

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.5.4.20]

The `ClinicalDocument` template records constraints on all NHSN HAI Reports (generic constraints). Additional constraints are noted in the specialization templates for single-patient and population-summary reports, and in the templates for specific report types. For the templates for this report review [Section 3](#) of this document.

### 4.2 (2.1.1 Top-level Element)

In a CDA document, the top-level element, also called the document element, is `ClinicalDocument`, in the `urn:hl7-org:v3` namespace.

### 4.3 (2.1.2 Document Information)

The first header information in a CDA document is about the document itself: what kind of document it is; its language, confidentiality status, and title; and its succession management detail.

For all templates specified in this document, the `templateId` is a required element.

1. In a document instance, a templated structure **SHALL** contain a `templateId` to assert conformance to this Implementation Guide. (CONF: 4503).
2. A `templateId` element **SHALL** be present representing conformance to the constraints for a specific report type. (CONF:4504).
3. **SHALL NOT** contain [1..1] `templateId/@extension` (CONF:4505)

This specification is for the U.S. realm.

4. **SHALL** contain [1..1] `realmCode/@code="US"` **STATIC** (CONF:4506)

CDA requires that a `ClinicalDocument/typeId` be present to identify the constraints imposed by CDA Release 2.0, essentially acting as a CDA version identifier. The effect of the CDA Release 2.0 requirement is:

The value of `typeId/@root` shall be

2.16.840.1.113883.1.3 and the value of

`typeId/@extension` shall be POCD\_HD000040. [CDA R2]

**Figure 2 (Figure 5: CDA header – template identifiers example)**

```
<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">

  <realmCode code="US"/>

  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>

  <!-- Conformant to HAI Generic Constraints -->
  <templateId root="2.16.840.1.113883.10.20.5.4.20" />

  <!-- Conformant to the HAI Constraints for BSI Numerator Report -->
  <templateId root="2.16.840.1.113883.10.20.5.7" />

  ...
</ClinicalDocument>
```

CDA requires a code element that specifies the type of the clinical document.

5. **SHALL** contain [1..1] `code/@code="51897-7"` Healthcare Associated Infection Report (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:4507)

6. **SHALL** contain [1..1] `title` (CONF:4508)

CDA requires an `effectiveTime` element representing the time of document creation.

7. **SHALL** contain [1..1] `effectiveTime` (CONF:4509)

CDA requires a confidentiality code that indicates the sensitivity of the document. All HAI submissions carry the same value of "normal." Note that this designation does not affect local policy on safeguarding confidentiality of patient-identifiable personal health information.

8. **SHALL** contain [1..1] `confidentialityCode/@code="N"` Normal (CodeSystem: 2.16.840.1.113883.5.25 HL7 Confidentiality Code) **STATIC** (CONF:4510).

9. **SHALL** contain [1..1] `languageCode/@code="en-US"` **STATIC** (CONF:4511).

10. **SHALL** contain [1..1] `setId` (CONF:4512)

11. **SHALL** contain [1..1] `versionNumber` (CONF:4513)

12. If `versionNumber/@value` is greater than 1, a `relatedDocument` element **SHALL** be present where the value of `@typeCode` **SHALL** be RPLC (replace) and the value of `parentDocument/id` **SHALL** be

populated with the `ClinicalDocument/id` of the document being replaced. In all cases (regardless of the version number), values of `APND` and `XFRM` **SHALL NOT** be used for `relatedDocument/@typeCode`. (CONF:4514).

**Figure 3 (Figure 6: CDA header – document information example)**

```
<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">
  ...
  <id root="2.16.840.1.113883.3.117.1.1.5.2.1.1.2"
    extension="20202201"/>

  <code codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"
    code="51897-7"
    displayName="Healthcare Associated Infection Report"/>

  <title>Bloodstream Infection Report (BSI)</title>

  <effectiveTime value="20061219"/>

  <confidentialityCode codeSystem="2.16.840.1.113883.5.25"
    code="N" />

  <languageCode code="en-US"/>

  <setId root="2.16.840.1.113883.3.117.1.1.5.2.1.1.1"
    extension="31"/>
  <versionNumber value="1"/>

  ...
</ClinicalDocument>
```

#### 4.4 (2.2.2 Header Constraints, HAI Single-Patient Reports)

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.5.4.1]

This template records the constraints specific to HAI single-patient reports. Constraints common to all HAI reports are recorded in this template.

In the `recordTarget` element, which is required by CDA, an `id` element representing the patient ID assigned by the facility is required. Additional `id` elements representing secondary patient IDs and a United States Social Security Number (`id/@root 2.16.840.1.113883.4.1`) may also be present.

In a single-patient report, the author may be software or may be a person in the role of infection control professional (ICP). The CDA Release 2.0 requirement is:

An `author` element shall be present. The `author` element shall contain a `time` element that represents the time of authoring of the information, and an `assignedAuthor` element that represents the author of the information. The `assignedAuthor` element shall contain an `id` element. [CDA R2]

In the `componentOf/encompassingEncounter` element,

- The `effectiveTime/low` element represents the date admitted to the facility.
  - Some report types also record whether the patient was an outpatient.
  - Physical location is recorded in `location/healthCareFacility/id`, where the value of `@root` represents the facility OID assigned by NHSN. (Most single-patient report types also require `@extension`, representing the facility's unit identifier, such as "9W", and `healthCareFacility/code` representing the type of location. See the sections on [report-specific constraints](#) to see if this is required for the report. The Immunization, Procedure, and Laboratory-identified Organism Reports do not require this information.)
1. Conforms to Healthcare Associated Infection Report Template (`templateId: 2.16.840.1.113883.10.20.5.4.20`).
  2. **SHALL** contain [1..1] `recordTarget/patientRole` (CONF:3084).
    - a. This `recordTarget/patientRole` **SHALL** contain [1..\*] `id` (CONF:3085).
      - i. Such `ids` **SHALL** contain `@root` (CONF:3087).
      - ii. Such `ids` **SHALL** contain `@extension` (CONF:3088).
    - b. This `recordTarget/patientRole` **SHALL** contain [1..1] `patient` (CONF:3220).
      - i. This `patient` **MAY** contain [0..1] `name` (CONF:3221).
      - ii. This `patient` **SHALL** contain [1..1] `administrativeGenderCode/@code` (CodeSystem: 2.16.840.1.113883.5.1 HL7 Gender Codes) **STATIC** (CONF:3222).
      - iii. This `patient` **SHALL** contain [1..1] `birthTime` (CONF:3223).
  3. The author **MAY** be software or **MAY** be a person in the role of infection control professional (ICP). (CONF:3089).
  4. **SHALL** contain [1..1] `componentOf/encompassingEncounter` (CONF:3090).
    - a. This `componentOf/encompassingEncounter` **SHALL** contain [1..1] `effectiveTime/low` (CONF:3091).
    - b. This `componentOf/encompassingEncounter` **SHALL** contain [1..1] `location/healthCareFacility/id` (CONF:3092).

**Figure 4 (Figure 9: CDA header – recordTarget example)**

```
<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">
  ...
  <recordTarget>
    <patientRole>
      <!-- Patient ID - scoped by facility -->
      <id root="2.16.840.1.113883.3.117.1.1.5.1.1.1"
        extension="123456" />
      <patient>
        <name>
          <family>Nuclear</family>
          <given>Ned</given>
        </name>
        <administrativeGenderCode
          codeSystem="2.16.840.1.113883.5.1"
          codeSystemName="HL7 Gender codes"
          code="M" />
        <birthTime value="19320924" />
      </patient>
    </patientRole>
  </recordTarget>
  ...
</ClinicalDocument>
```

**Figure 5 (Figure 10: CDA header – facility location and admission date, single-patient report example)**

```
<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">
  ...
  <componentOf>
    <encompassingEncounter>

      <id root="2.16.840.1.113883.3.117.1.1.5.2.1.1.3"
        extension="31"/>

      <code codeSystem="2.16.840.1.113883.5.4"
        codeSystemName="HL7 ActCode"
        code="AMB"
        displayName="Ambulatory"/>

      <effectiveTime>
        <!-- Date Admitted to Facility -->
        <low value="20061218"/>
      </effectiveTime>

      <location>
        <healthCareFacility>
          <!-- Facility ID -->
          <id root="2.16.840.1.113883.3.117.1.1.5.1.1" extension="9W"/>
          <code codeSystem="2.16.840.1.113883.6.259"
            codeSystemName="HL7 HealthcareServiceLocation"
            code="1029-8"
            displayName="Medical/Surgical critical care"/>
          </healthCareFacility>
        </location>
      </encompassingEncounter>
    </componentOf>
    ...
  </ClinicalDocument>
```

#### **4.5 (2.1.4 The Author, Custodian and legalAuthenticator)**

The author, which may be software or may be a person in the role of infection control professional (ICP). is required in all single-patient reports. The CDA Release 2.0 requirement is:

An author element shall be present. The author element shall contain a time element that represents the time of authoring of the information, and an assignedAuthor element that represents the author of the information. The assignedAuthor element shall contain an id element. [CDA R2]

CDA also requires the custodian be recorded; the NHSN is the custodian of NHSN HAI Reports.

13. **SHALL** contain [1..1] `custodian/assignedCustodian/representedCustodianOrganization/id/@root="2.16.840.1.114222.4.3.2.11"` (CONF:4515).

CDA requires that a `legalAuthenticator` element be present if the document has been legally authenticated. Local policy may delegate the function of legal authentication to a device or system that generates the CDA document. In these cases, the legal authenticator must still be a person accepting responsibility for the document content, not the device or system.

**Figure 6 (Figure 7: CDA header – author, custodian, and legalAuthenticator example)**

```

<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">
  ...
  <author>
    <time value="20061219"/>
    <assignedAuthor>
      <id root="2.16.840.1.113883.3.117.1.1.5.1.1.2"
        extension="anAuthorID"/>
    </assignedAuthor>
  </author>

  <custodian>
    <assignedCustodian>
      <representedCustodianOrganization>
        <id root="2.16.840.1.114222.4.3.2.11"/>
      </representedCustodianOrganization>
    </assignedCustodian>
  </custodian>

  <legalAuthenticator>
    <time value="20061224"/>
    <signatureCode code="S"/>
    <assignedEntity>
      <id root="2.16.840.1.113883.3.117.1.1.5.1.1.2"
        extension="aLegalAuthenticatorID"/>
    </assignedEntity>
  </legalAuthenticator>
  ...
</ClinicalDocument>

```

## 4.6 (2.1.5 Document body)

An HAI Report uses the CDA `structuredBody`. Specified sections are required in each report type; see the section on [report-specific constraints](#). Additional sections that may be present in the file will not be processed by NHSN.

14. **SHALL** contain [1..1] `component/structuredBody` (CONF:4516)
15. The `structuredBody` element **SHALL** contain a `component` element for each section required by the particular report type. Additional sections may be present but their content will not be processed by NHSN. (CONF:4517).

**Figure 7 (Figure 8: Structured body example)**

```
<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">
  ...
  <component>
    <structuredBody>
      <component>
        <section>
          ...
        </section>
        ...
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

#### **4.7 (2.3.1 HAI Section Generic Constraints)**

[section: templateId 2.16.840.1.113883.10.20.5.4.3]

This template records the constraints that apply to all sections specified in the NHSN HAI Implementation Guide. Each `section` element conforming to constraints in this guide will have a `templateId`, a `code`, a `title`, a `narrative block` (`text` element), and the specific entries required by the report type. Top-level sections conforming to other guides are allowed and need not conform to these constraints.

1. **SHALL** contain [1..1] `code/@code` (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:3171).
2. **SHALL** contain [1..1] `title` (CONF:3172).
3. **SHALL** contain [1..1] `text` (CONF:3173).
4. **SHALL** contain [1..\*] `entry` (CONF:3174).

**Figure 8 (Figure 12: Section example)**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.5.5.15"/>
  <code codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"
    code="18769-0"
    displayName="Findings Section"/>
  <title>Bug-Drug Tests</title>
  <text>
    ...
  </text>
  <entry>
    ...
  </entry>
</section>
```

#### **4.8 (2.3.2 Narrative Block and @typeCode = "DRIV")**

The Narrative Block in the CDA file is not detailed in this document because of the almost infinite set of semantic structures that can be developed. It is worth noting that the Narrative Block is required for the CDA file, but it can be left as an

empty shell if the facility does not wish to use the section. Many facilities do use the narrative block because it allows the user to have a human view of the record that can be reviewed by an IP before the file is imported into the NHSN system. The example of the [BIS-Num Example](#) CDA file contains examples of the narrative block.

The CDC has created a generate-narrative file that can be used when generating a narrative block. IT groups that are interested in using the generate-narrative file can request the file and get assistance implementing it with their system by sending an email to Marla Albitz at [malbitz@cdc.gov](mailto:malbitz@cdc.gov).

## 5. Generic Constraints for Primary Bloodstream Infection (BSI) Report

The following section will help guide IT groups in developing the generic constraints section for a Primary Bloodstream Infection (BSI) Report CDA file if their hospital system does not have the capability to generate this file for them. Only the required sections needed for the BSI report will be noted in this section.

### 5.1 Common Header Constraints

The common header constraints are explained in [Section 4 \(2 NHSN HAI Generic Constraints\)](#) of this document.

### 5.2 (3.2 HAI Bloodstream Infection Report (BSI))

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.5.7]

The BSI Report records a bloodstream infection. The preferred title is “Bloodstream Infection Report (BSI)”.

The date of the infection is recorded as effectiveTime in the Infection-type Observation (templateId 2.16.840.1.113883.10.20.5.6.23).

1. Conforms to Header Constraints, HAI Single-Patient Reports Template (templateId: 2.16.840.1.113883.10.20.5.4.1).
2. **SHALL** contain [1..1] `componentOf/encompassingEncounter/location/healthCareFacility/id/@extension` (CONF:3114).
3. **SHALL** contain [1..1] `componentOf/encompassingEncounter/location/healthCareFacility/code/@code`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.19 NHSNHealthcareServiceLocationCode **DYNAMIC** (CONF:3115).
4. **SHALL** contain [1..1] `component/structuredBody` (CONF:2848).
  - a. This component/structuredBody **SHALL** contain [1..1] `component` (CONF:2849) such that it
    - i. **SHALL** contain [1..1] **Infection Risk Factors Section in a BSI Report** (templateId:2.16.840.1.113883.10.20.5.5.1) (CONF:2850).

- b. This component/structuredBody **SHALL** contain [1..1] component (CONF:2851) such that it
  - i. **SHALL** contain [1..1] **Infection Details Section in a BSI Report** (templateId:2.16.840.1.113883.10.20.5.5.6) (CONF:2852).
- c. This component/structuredBody **SHALL** contain [1..1] component (CONF:2853) such that it
  - i. **SHALL** contain [1..1] **Findings Section** (templateId:2.16.840.1.113883.10.20.5.5.15) (CONF:2854).

**Figure 9 (Figure 13: Report-specific constraints example)**

```

<ClinicalDocument
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:mif="urn:hl7-org:v3/mif" xmlns="urn:hl7-org:v3">
  ...
  <templateId root="2.16.840.1.113883.10.20.5.7">
  ...
  <title>Bloodstream Infection Report (BSI)</title>
  ...
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.5.5.1"/>
          ...
        </section>
      </component>

      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.5.5.6"/>
          ...
        </section>
      </component>

      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.5.5.15"/>
          ...
        </section>
      </component>

    </structuredBody>
  </component>
</ClinicalDocument>

```

### **5.3 (4.1.1 Infection Risk Factors Section in a BSI Report)**

[section: templateId 2.16.840.1.113883.10.20.5.5.1]

In a BSI Report, the Infection Risk Factors Section contains Infection Risk Factors Observations and/or Infection Risk Factors Measurement Observations (templateIds 2.16.840.1.113883.10.20.5.2.1.1.1 and

2.16.840.1.113883.10.20.5.2.1.1.2). The particular observations required depend on the location type, specified by `ClinicalDocument/componentOf/encompassingEncounter/location / healthcareFacility/code`.

Some information requirements in this template depend on the location reporting the infection: ICU/Other (ICU or any other location except for Specialty Care Areas), SCA (Specialty Care Areas), or NICU (Neonatal Intensive Care Unit).

1. Conforms to HAI Section Generic Constraints Template (`templateId: 2.16.840.1.113883.10.20.5.4.3`).
2. **SHALL** contain [1..1] `code/@code="51898-5"` Risk Factors Section (`CodeSystem: 2.16.840.1.113883.6.1 LOINC`) **STATIC** (CONF:2131).
3. If the location type represents an ICU/Other or NICU location, an `entry` element **SHALL** be present containing a Risk Factors Observation (`templateId 2.16.840.1.113883.10.20.5.2.1.1.1`) representing whether a central line was present. (CONF:2132).
4. If the location type represents an SCA location, an `entry` element **SHALL** be present containing a Risk Factors Observation (`templateId 2.16.840.1.113883.10.20.5.2.1.1.1`) representing whether a permanent central line was present, and an `entry` element containing a Risk Factors Observation (`templateId 2.16.840.1.113883.10.20.5.2.1.1.1`) representing whether a Temporary Central Line was present. (CONF:2133).
5. If the location type represents an NICU location, an `entry` element **SHALL** be present containing an Infection Risk Factors Observation (`templateId 2.16.840.1.113883.10.20.5.2.1.1.1`) representing whether a (non-umbilical) central line was present, an `entry` element **SHALL** be present containing a Risk Factors Observation (`templateId 2.16.840.1.113883.10.20.5.2.1.1.1`) representing whether an umbilical catheter was present, and an `entry` element **SHALL** be present containing an Infection Risk Factors Measurement Observation (`templateId 2.16.840.1.113883.10.20.5.2.1.1.2`) representing the birth weight. (CONF:2134).

**Figure 10 (Figure 14: Risk factors section in a BSI report example)**

```
<section>
  <templateId root="2.16.840.1.113883.10.20.5.5.1"/>
  <code codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        code="51898-5"
        displayName=" Risk Factors Section"/>
  <title>Risk Factors</title>
  ...
</section>
```

## 5.4 (5.2.32 Infection Risk Factors Measurement Observation)

[`observation: templateId 2.16.840.1.113883.10.20.5.2.1.1.2`]

This observation records a risk factor that reports a value, such as birth weight.

Both BSI and the Pneumonia Infection reports use the Infection Risk Factors Measurement Observation. The NHSN Protocol specifies which measurements are required for each report type. Those rules do not form part of the guide. The table below shows requirements at the time of publication.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2064).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2065).
3. **SHALL** contain [1..1] **@negationInd="false"** (CONF:4223).
4. **SHALL** contain [1..1] **code/@code** (CONF:2066).
5. **SHALL** contain [1..1] **statusCode/@code="completed"** Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2067).
6. **SHALL** contain [1..1] **value** (CONF:2068).
  - a. This value **SHALL** contain [1..1] **@xsi:type="PQ"** (CONF:4537).

**Table 4 (Table 28: Codes for Infection Risk Factors Measurement Observation)**

Code	Display Name	Code System	Code System Name
364589006	Birth weight	2.16.840.1.113883.6.96	SNOMED CT

**Figure 11 (Figure 58: Infection risk factors measurement observation example)**

```

<entry>
  <observation classCode="OBS" moodCode="EVN" negationInd="false">
    <templateId root="2.16.840.1.113883.10.20.5.2.1.1.2"/>
    <code code="364589006" codeSystem="2.16.840.1.113883.6.96"
      displayName="Birth weight"/>
    <statusCode code="completed"/>
    <value xsi:type="PQ" value="700" unit="g"/>
  </observation>
</entry>

```

## 5.5 (5.2.33 Infection Risk Factors Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.1.1.1]

This observation records the presence of infection risk factors. See also the [Infection Risk Factors Measurement Observation](#).

The NHSNInfectionRiskFactorsCode Value Set, shown below in Table 29, includes infection risk factors for all reports in this guide. The NHSN Protocol specifies which risk factors are to be recorded in each report type. Those rules do not form part of the guide.

If the risk factor is present, set the value of **@negationInd** to false. If the risk factor is not present, set the value of **@negationInd** to true.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2069).

2. **SHALL** contain [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2070).
3. **SHALL** contain **@negationInd** (CONF:2071).
4. **SHALL** contain [1..1] **code/@code**="ASSERTION" Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2072).
5. **SHALL** contain [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2073).
6. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.6 NHSNInfectionRiskFactorsCode **STATIC** 20090130 (CONF:2074).

**Table 5 (Table 29: Infection Risk Factors Value Set)**

Value Set: NHSNInfectionRiskFactorsCode 2.16.840.1.113883.13.6 Code systems: cdcNHSN 2.16.840.1.113883.6.277 or SNOMED CT 2.16.840.1.113883.6.96		
Code	Code System	Meaning
1002-5	cdcNHSN	(unspecified) central line
1003-3	cdcNHSN	permanent central line
1005-8	cdcNHSN	temporary central line
1001-7	cdcNHSN	umbilical catheter

**Figure 12 (Figure 59: Infection risk factors observation example)**

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.2.1.1.1"/>
  <code codeSystem="2.16.840.1.113883.5.4" code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
    codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    code="1003-3"
    displayName="permanent central line"/>
</observation>
```

## 5.6 (4.2.2 Infection Details Section in a BSI Report)

[section: templateId 2.16.840.1.113883.10.20.5.5.6]

1. Conforms to HAI Section Generic Constraints Template (templateId: 2.16.840.1.113883.10.20.5.4.3).
2. **SHALL** contain [1..1] **code/@code**="51899-3" Details Section (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:2129).
3. **SHALL** contain [1..1] **entry** (CONF:2197) such that it
  - a. **SHALL** contain [1..1] **Infection-type Observation** (templateId:2.16.840.1.113883.10.20.5.6.23) (CONF:2130).
4. If the patient died, an entry element **SHALL** be present containing a Death Observation (templateId 2.16.840.1.113883.10.20.5.6.12); if the patient did not die, an entry element **MAY** be present containing a Death

Observation (templateId 2.16.840.1.113883.10.20.5.6.12).  
(CONF:2163).

## 5.7 (5.2.34 Infection-type Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.6.23]

The Infection-type Observation is used in all infection reports. It is an assertion of the infection type, and contains `entryRelationships` to record the “criteria”—the information used to arrive at a diagnosis of the infection type.

The value of the `id` element must be globally unique and need not be an ID used outside the document. Its function within the document is to identify this infection as being the same as that recorded in the Infection Contributed to Death Observation, if present.

1. **SHALL** contain [1..1] `@classCode="OBS"` Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2095).
2. **SHALL** contain [1..1] `@moodCode="EVN"` Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2096).
3. **SHALL** contain [1..1] `@negationInd="false"` (CONF:4224).
4. **SHALL** contain [1..1] `id` (CONF:2097).
5. **SHALL** contain [1..1] `code/@code="ASSERTION"` Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:3025).
6. **SHALL** contain [1..1] `statusCode/@code="completed"` Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2099).
7. **SHALL** contain [1..1] `effectiveTime` (CONF:2100).
8. **SHALL** contain [1..1] `value/@code`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.20 NHSNInfectionTypeCode **DYNAMIC** (CONF:2101).
9. **SHALL** contain [1..1] `entryRelationship` (CONF:2215) such that it
  - a. **SHALL** contain [1..1] `@typeCode="SPRT"` Supports (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:2103).
  - b. **SHALL** contain [1..1] **Criteria of Diagnosis Organizer** (templateId:2.16.840.1.113883.10.20.5.6.11) (CONF:2102).
10. Steps 10 thru 11 were deleted because they do not apply to the BSI report.
12. If the report is a BSI Report, an `entryRelationship` element **SHALL** be present where the value of `@typeCode` is `COMP`, containing a Bloodstream Infection Evidence Type Observation (templateId 2.16.840.1.113883.10.20.5.6.4). (CONF:2608).
13. Steps 13 thru 16 were deleted because they did not apply to the BSI report.

**Table 6 (Table 30: Infection Type Value Set)**

Value Set: NHSNInfectionTypeCode 2.16.840.1.113883.13.20 Code System: cdcNHSN 2.16.840.1.113883.6.277 or SNOMED CT 2.16.840.1.113883.6.96		
Code	Code System	Meaning
431193003	SNOMED CT	Bloodstream Infection
233604007	SNOMED CT	Pneumonia
433202001	SNOMED CT	Surgical Site Infection
68566005	SNOMED CT	Urinary Tract Infection
1792-1	cdcNHSN	MDRO Infection
1795-4	cdcNHSN	CDAD Infection
Generic (Custom) Infection Report types		
312158001	SNOMED CT	Gastrointestinal Infection
1796-2	cdcNHSN	Infection of the Reproduction System
1797-0	cdcNHSN	Infection of the Ear/Eyes/Nose or Throat
50417007	SNOMED CT	Lower respiratory Infection
128402005	SNOMED CT	Infection of the cardiovascular system
128116006	SNOMED CT	Infection of the Central Nervous System
19824006	SNOMED CT	Skin or Soft Tissue Infection
1798-8	cdcNHSN	Bone or Joint Infection
91302008	SNOMED CT	Systemic Infection

**Figure 13 (Figure 60: Infection-type observation example)**

```

<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.6.23"/>
  <id root="2.16.840.1.113883.3.117.1.1.5.1.1.XXX"
  extension="21987654321"/>
  <code codeSystem="2.16.840.1.113883.5.4" code="ASSERTION"/>
  <statusCode code="completed"/>
  <effectiveTime value="20081205"/>
  <value xsi:type="CD"
    codeSystem="2.16.840.1.113883.6.277"
    codeSystemName=" cdcNHSN"
    code="1795-4"
    displayName="CDAD Infection">
  </value>

  <entryRelationship typeCode="SPRT">
    <organizer>
      <templateId root="2.16.840.1.113883.10.20.5.6.11"/>
    </organizer>
  </entryRelationship>

  ...
</observation>

```

## 5.8 (5.1.2 Criteria of Diagnosis Organizer)

[organizer: templateId 2.16.840.1.113883.10.20.5.6.11]

This organizer groups together the criteria used in the diagnosis of an infection. Each criterion is recorded as a Criterion of Diagnosis Observation. The organizer appears within an Infection-type Observation.

The Criteria of Diagnosis Organizer is used in several report types. The NHSN Protocol specifies which criteria are to be recorded for each report type. Those rules do not form part of this template. The NHSN submission requirement is that, in a given report type, a Criterion of Diagnosis Observation must be present for every datum required by the NHSN Protocol for that report type, with an appropriate value for @negationInd.

1. **SHALL** contain [1..1] @classCode="CLUSTER" Cluster (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2091).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2092).
3. **SHALL** contain [1..1] statusCode/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2093).
4. **SHALL** contain [1..\*] component (CONF:2195).
  - a. Such components **SHALL** contain [1..1] Criterion of Diagnosis Observation (templateId:2.16.840.1.113883.10.20.5.6.10) (CONF:2094).

**Figure 14 (Figure 22: Criteria of diagnosis organizer example)**

```
<organizer classCode="CLUSTER" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.6.11"/>
  <statusCode code="completed"/>
  <component>
    <observation>
      ...
    </observation>
  </component>
  ...
</organizer>
```

## 5.9 (5.2.7 Bloodstream Infection Evidence Type Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.6.4]

This observation records whether the bloodstream infection being reported was confirmed by a positive blood culture or inferred from clinical symptoms.

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2051).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2052).
3. **SHALL** contain [1..1] @negationInd="false" (CONF:4216).

4. **SHALL** contain [1..1] **code/@code="ASSERTION"** Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2053).
5. **SHALL** contain [1..1] **statusCode/@code="completed"** Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2056).
6. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.7 NHSNBloodStreamInfectionEvidenceTypeCode **STATIC** 20090130 (CONF:2057).

**Table 7 (Table 15: Bloodstream Infection Evidence Type Value Set)**

Value Set: NHSNBloodStreamInfectionEvidenceTypeCode 2.16.840.1.113883.13.7 Code System: cdcNHSN 2.16.840.1.113883.6.277		
Code	Code System	Meaning
1613-9	cdcNHSN	Laboratory-confirmed bloodstream infection

**Figure 15 (Figure 32: Bloodstream infection evidence type example)**

```

<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.6.4"/>
  <code codeSystem="2.16.840.1.113883.5.4"
    code="ASSERTION" />
  <statusCode code="completed" />
  <value xsi:type="CD"
    codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    value="1613-9"
    displayName=" Laboratory-confirmed bloodstream infection" />
</observation>

```

## 5.10 (5.2.13 Death Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.6.12]

This observation records whether the patient died and, if so, whether the infection being recorded contributed to that death.

If the patient died, set the value of @negationInd to false. If the patient did not die, set the value of @negationInd to true.

If the patient died, the Death Observation must also indicate whether the infection contributed to the death using an entryRelationship element containing an Infection Contributed to Death Observation. An inversionInd attribute on this entryRelationship element indicates that it should be interpreted as if the roles of the source and target entries were reversed. Thus, the observation reports whether the infection “supported” (contributed to) the death. The CAUS value does not have the force of “cause of death” on a death certificate; it indicates that the infection is causal or contributory to the death.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2081).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2082).

3. **SHALL** contain `@negationInd` (CONF:2083).
4. **SHALL** contain `[1..1] code/@code="ASSERTION"` Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2084).
5. **SHALL** contain `[1..1] statusCode/@code="completed"` Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2085).
6. **SHALL** contain `[1..1] value/@code="419099009"` Dead (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2086).
7. If the patient died, an `entryRelationship` element **SHALL** be present where the value of `@typeCode` is CAUS (causal or contributory) and the value of `@inversionInd` is true. The `entryRelationship` **SHALL** contain an Infection Contributed to Death Observation (`templateId` 2.16.840.1.113883.10.20.5.6.22). If the infection contributed to death, the value of `entryRelationship/@negationInd` **SHALL** be false. If the infection did not contribute to the death, the value of `@negationInd` **SHALL** be true. (CONF:2599).

**Figure 16 (Figure 38: Death observation example – patient did not die)**

```

<!-- "Dead" is negated = patient did not die -->
<observation classCode="OBS" moodCode="EVN" negationInd="true">
  <templateId root="2.16.840.1.113883.10.20.5.6.12"/>
  <code codeSystem="2.16.840.1.113883.5.4"
        code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
        code="419099009"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED"
        displayName="Dead"/>
</observation>

```

## 5.11 (5.2.31 Infection Contributed to Death Observation)

[observation: `templateId` 2.16.840.1.113883.10.20.5.6.22]

In some HAI Reports this observation is required in a Death Observation if the patient died.

1. **SHALL** contain `[1..1] @classCode="OBS"` Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2045).
2. **SHALL** contain `[1..1] @moodCode="EVN"` Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2046).
3. **SHALL** contain `[1..1] code/@code="ASSERTION"` Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2049).
4. **SHALL** contain `[1..1] id` (CONF:2047).
5. The value of the `id` **SHALL** be the same as the value of the `id` element in the Infection-type Observation (`templateId` 2.16.840.1.113883.10.20.5.6.23). (CONF:2048).
6. **SHALL** contain `[1..1] statusCode/@code="completed"` Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2050).

**Figure 17 (Figure 57: Infection contributed to death observation example)**

```
<!-- patient did die -->
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.6.12"/>
  <code codeSystem="2.16.840.1.113883.5.4"
        code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
        code="419099009"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED"
        displayName="Dead"/>

  <!--infection did not contribute to death -->
  <entryRelationship typeCode="CAUS" inversionInd="true"
negationInd="true">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.5.6.22"/>
      <id root="2.16.840.1.113883.3.117.1.1.5.1.1.XXX"
extension="21987654321"/>
      <code codeSystem="2.16.840.1.113883.5.4"
            code="ASSERTION" />
      <statusCode code="completed"/>
    </observation>
  </entryRelationship>
</observation>
```

## 5.12 (4.4 Findings Section in an Infection Report)

[section: templateId 2.16.840.1.113883.10.20.5.5.15]

The Findings Section records whether infection organisms were identified and, if so, records details about them. Several NHSN Report types, such as the BSI and SSI Reports, include this section. The LOINC code and `templateId` are the same in all report types, and the information recorded is the same in each report type, with the following exceptions: in an MDRO/CDAD Infection Report, two additional clinical statements are required; the Generic Infection Report does not require an MDRO Observation.

1. Conforms to HAI Section Generic Constraints Template (`templateId`: 2.16.840.1.113883.10.20.5.4.3).
2. **SHALL** contain [1..1] `code/@code="18769-0"` Findings Section (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:2120).
3. If no pathogens were identified, the Findings Section **SHALL** contain a single entry element containing a Pathogen Identified Observation (`templateId` 2.16.840.1.113883.10.20.5.2.5.1) reporting that no pathogens were identified. (CONF:2605).
4. If pathogens were identified, the Findings Section **SHALL** contain at least one and no more than three entry elements containing a Findings Organizer (`templateId` 2.16.840.1.113883.10.20.5.6.14) reporting pathogens identified. (CONF:2207).
5. If pathogens were identified, and the report is not a Generic Infection Report, an entry element where the value of `@typeCode` is COMP **SHALL** be

- present containing an MDRO Observation (templateId 2.16.840.1.113883.10.20.5.6.24). (CONF:2123).
6. If pathogens were identified and the report is an MDRO/CDAD Infection Report, an entry element **SHALL** be present where the value of @typeCode is COMP, containing a Significant Pathogens Observation (templateId 2.16.840.1.113883.10.20.5.6.41). (CONF:2208).
  7. If pathogens were identified and the report is an MDRO/CDAD Infection Report, an entry element **SHALL** be present where the value of @typeCode is COMP, containing a CDAD Observation (templateId 2.16.840.1.113883.10.20.5.6.5). (CONF:2127).

**Figure 18 (Figure 19: Findings section example)**

```

<section>
  <templateId root="2.16.840.1.113883.10.20.5.5.15"/>
  <code codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        code="18769-0"
        displayName="Findings Section"/>
  <title>Findings</title>
  ...
</section>

```

### 5.13 (5.2.41 Pathogen Identified Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.5.1]

A Pathogen Identified Observation either represents a pathogen identified (in which case it appears in an organizer with detail about the pathogen) or records that no pathogens were identified.

In many cases, the value-set table provides a code for an unspecified species, for example, "Acidaminococcus species" (SNOMED CT 131202007, NHSN ACISP), for use when a more precise code is not available. The code for an unspecified species is preferred to a genus-level code.

The NHSN Pathogen Code Value Set includes a code for the case in which no pathogens were identified.

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2040).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2041).
3. **SHALL** contain [1..1] code/@code="41852-5" Microorganism identified (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:2042).
4. **SHALL** contain [1..1] statusCode/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2043).
5. **SHALL** contain [1..1] value/@code, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.16 NHSNPathogenCode **DYNAMIC** (CONF:2044).

**Table 8 (Table 34: Pathogen Value Set (excerpt))**

Value Set: NHSNPathogenCode 2.16.840.1.113883.13.16 Code System: SNOMED CT 2.16.840.1.113883.6.96 or cdcNHSN 2.16.840.1.113883.6.277			
The full table is shown in <u>Pathogen Value Set</u> found in the Release 7 document			
Category	cdcNHSN	Display Name	SDO Fully Specified Name
--	3119-7	No pathogen identified	
Category	SNOMED CT Concept ID	Display Name	SNOMED CT Fully Specified Name
BACTERIUM	372391001	Abiotrophia species	Abiotrophia species (organism)
PARASITE	50875003	Acanthamoeba	Acanthamoeba (organism)
BACTERIUM	413423003	Achromobacter spp.	Achromobacter species (organism)
BACTERIUM	413424009	Achromobacter xylosoxidans	Achromobacter xylosoxidans (organism)
BACTERIUM	116197008	Staphylococcus coagulase negative	Staphylococcus, coagulase negative (organism)
BACTERIUM	48321006	Clostridium symbiosum	Clostridium symbiosum (organism)
...			

**Figure 19 (Figure 67: Pathogen identified observation example)**

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.2.5.1"/>
  <code codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"
    code="41852-5"
    displayName="Microorganism identified"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    code="116197008"
    displayName="Staphylococcus, coagulase negative (organism)"/>
</observation>
```

### 5.14 (5.1.3 Findings Organizer)

[organizer: templateId 2.16.840.1.113883.10.20.5.6.14]

Each Findings Organizer represents a set of information concerning a single pathogen identified. The organizer contains two `component` elements that record the pathogen and its rank in regard to the other pathogens identified, and can contain additional `component` elements recording drug-susceptibility test findings.

For bacterial pathogens, at least one drug-susceptibility test result is required. For nonbacterial pathogens, drug-susceptibility test results are not required.

1. **SHALL** contain [1..1] @classCode="CLUSTER" Cluster (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2075).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2076).
3. **SHALL** contain [1..1] statusCode/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2077).
4. **SHALL** contain [1..1] component (CONF:2200) such that it
  - a. **SHALL** contain [1..1] Pathogen Identified Observation (templateId:2.16.840.1.113883.10.20.5.2.5.1) (CONF:2078).
5. **SHALL** contain [1..1] component (CONF:2201) such that it
  - a. **SHALL** contain [1..1] Pathogen Ranking Observation (templateId:2.16.840.1.113883.10.20.5.2.5.1.1) (CONF:2079).
6. If the pathogen is a bacterial pathogen, at least one component element **SHALL** be present containing a Drug-susceptibility Test Observation (templateId 2.16.840.1.113883.10.20.5.2.5.1.2). (CONF:2204).

**Figure 20 (Figure 23: Findings organizer example)**

```

<organizer classCode="CLUSTER" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.6.14"/>

  <component>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.5.2.5.1"/>
      ...
    </observation>
  </component>

  <component>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.5.2.5.1.1"/>
      ...
    </observation>
  </component>

  <component>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.5.2.5.1.2"/>
      ...
    </observation>
  </component>
</organizer>

```

### 5.15 (5.2.43 Pathogen Ranking Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.5.1.1]

The NHSN pathogen findings record up to three pathogens. This observation records the relative importance of a pathogen in that set with respect to its role in the infection.

The value is a coded ordinal, where the value of @code is the number 1 or 2 or 3: 1 represents the highest-ranked pathogen of up to three pathogens recorded.

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2032).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2033).
3. **SHALL** contain [1..1] code/@code="ASSERTION" Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2034).
4. **SHALL** contain [1..1] statusCode/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2035).
5. **SHALL** contain [1..1] value (CONF:2039).
6. The value of value/@xsi:type **SHALL** be CO(Coded Ordinal), the value of value/@codeSystem **SHALL** be 2.16.840.1.113883.6.277 cdcNHSN, and the value of value/@code **SHALL** be the number 1 or 2 or 3, where 1 represents the highest-ranked pathogen of up to three pathogens recorded. (CONF:2915).

**Figure 21 (Figure 68: Pathogen ranking observation example)**

```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.2.5.1.1" />
  <code codeSystem="2.16.840.1.113883.5.4"
    codeSystemName="HL7"
    code="ASSERTION" />
  <statusCode code="completed" />
  <value xsi:type="CO"
    codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    code="1"
    displayName="Pathogen ranking 1" />
</observation>

```

## 5.16 (5.2.15 Drug-susceptibility Test Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.5.1.2]

This observation uses two codes, one to identify the drug, and the other to record the pathogen's susceptibility to it. A LOINC code represents a methodless isolate drug-susceptibility test, an HL7 ObservationInterpretation code represents the susceptibility finding.

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2028).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2029).
3. **SHALL** contain [1..1] code/@code, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.15 NHSNDrugSusceptibilityTestCode **DYNAMIC** (CONF:2030).

4. **SHALL** contain [1..1] `statusCode/@code="completed"` Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2036).
5. **SHALL** contain [1..1] `interpretationCode` (CONF:2031).
6. If the interpretation result is known, the value of `interpretationCode/@code` **SHALL** be selected from Value Set 2.16.840.1.113883.13.13 NHSNDrugSusceptibilityFindingCode **STATIC** 20080130. If the drug was not tested, the value of `@nullFlavor` **SHALL** be `NASK`. (CONF:2135).

**Table 9 (Table 18: Drug-susceptibility Tests Value Set (excerpt))**

Value Set: NHSNDrugSusceptibilityTestsCode 2.16.840.1.113883.13.15 Code System: LOINC 2.16.840.1.113883.6.1		
The full table is shown in <a href="#">Drug-susceptibility Tests Value Set</a> found in the Release 7 document		
Code	Code System	Meaning
18860-7	LOINC	Amikacin Susc Islt
18862-3	LOINC	Amoxicillin+Clav Susc Islt
18907-6	LOINC	Clarithro Susc Islt
19000-9	LOINC	Vancomycin Susc Islt
...	LOINC	...

**Table 10 (Table 19: Drug-susceptibility Finding Value Set)**

Value Set: NHSNDrugSusceptibilityFindingCode 2.16.840.1.113883.13.13 Code System: HL7 ObservationInterpretation 2.16.840.1.113883.5.83		
Code	Code System	Meaning
S	HL7 ObservationInterpretation	Susceptible
I	HL7 ObservationInterpretation	Intermediate
	HL7 ObservationInterpretation	Resistant

**Figure 22 (Figure 40: Drug-susceptibility test observation example)**

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root=" 2.16.840.1.113883.10.20.5.2.5.1.2"/>
  <code codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"
    code="19000-9"
    displayName="Vancomycin Susc Islt"/>
  <statusCode code="completed"/>
  <interpretationCode codeSystem="2.16.840.1.113883.5.83"
    codeSystemName="HL7 Observation Interpretation"
    code="S"
    displayName="susceptible"/>
</observation>
```

## 5.17 (5.2.35 MDRO Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.6.24]

This observation records whether the primary infection being reported was caused by a multi-drug-resistant organism (MDRO). It is a general or summary observation not associated with any individual pathogen in the Findings Section.

If the infection organism was multi-drug resistant, set the value of @negationInd to false. If the infection organism was not multi-drug resistant, set the value of @negationInd to true.

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2023).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2024).
3. **SHALL** contain @negationInd (CONF:2025).
4. **SHALL** contain [1..1] code/@code="ASSERTION" Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2026).
5. **SHALL** contain [1..1] statusCode/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2037).
6. **SHALL** contain [1..1] value/@code="1792-1" MDRO Infection (CodeSystem: 2.16.840.1.113883.6.277 cdcNHSN) **STATIC** (CONF:2027).

**Figure 23 (Figure 61: MDRO observation example)**

```
<!-- The observation is negated, i.e. MDRO=no -->
<observation classCode="OBS" moodCode="EVN" negationInd="true">
  <templateId root="2.16.840.1.113883.10.20.5.6.24"/>
  <code codeSystem="2.16.840.1.113883.5.4" code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
    codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    code="1792-1"
    displayName="MDRO Infection"/>
</observation>
```

**5.18 (5.2.56 Significant Pathogens Observation)**

[observation: templateId 2.16.840.1.113883.10.20.5.6.41]

This observation records the finding of up to three of the most significant pathogens. This is recorded separately from the drug-test Findings Organizer in the Findings Section of an HAI MDRO/CDAD Infection Report.

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2279).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2280).
3. **SHALL** contain [1..1] code/@code="41852-5" Microorganism Identified (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:2281).
4. **SHALL** contain [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2282).
5. **SHALL** contain [1..3] value/@code, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3194 NHSNSignificantPathogenCode **STATIC** 20090625 (CONF:2283).

**Table 11 (Table 47: Significant Pathogens Value Set)**

Value Set: NHSNSignificantPathogenCode 2.16.840.1.114222.4.11.3194 Code System: SNOMED CT 2.16.840.1.113883.6.96 or cdcNHSN 2.16.840.1.113883.6.277		
Code	Code System	Meaning
115329001	SNOMED CT	MRSA
417943000	SNOMED CT	MSSA
113727004	SNOMED CT	VRE
2015-6	cdcNHSN	MDR-KLEB
2010-7	cdcNHSN	MDR-ACINE
5933001	SNOMED CT	CDIF

**Figure 24 (Figure 84: Significant pathogens observation example)**

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.6.41"/>
  <code codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        code="41852-5"
        displayName="Microorganism identified"/>

  <value xsi:type="CD"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED"
        code="5933001"
        displayName="CDIF"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED"
        code="113727004"
        displayName="VRE"/>
</observation>
```

## 5.19 (5.2.8 CDAD Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.6.5]

This observation records whether the primary infection being reported involved a *C. difficile*-associated disease (CDAD). It is a general or summary observation not associated with any individual pathogen in the Findings Section.

If a *C. difficile*-associated disease was involved, set the value of @negationInd to false. If a *C. difficile*-associated disease was not involved, set the value of @negationInd to true.

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2284).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2285).
3. **SHALL** contain @negationInd (CONF:2614).
4. **SHALL** contain [1..1] code/@code="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2286).
5. **SHALL** contain [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2287).
6. **SHALL** contain [1..1] value/@code="1795-4" *C.*-difficile-associated disease (CodeSystem: 2.16.840.1.113883.6.277 cdcNHSN) **STATIC** (CONF:2288).

**Figure 25 (Figure 332: CDAD observation example)**

```
<!-- The observation is negated, i.e. CDAD=no -->
<observation classCode="OBS" moodCode="EVN" negationInd="true">
  <templateId root="2.16.840.1.113883.10.20.5.6.5"/>
  <code codeSystem="2.16.840.1.113883.5.4" code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
    codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    code="1795-4"
    displayName="C.difficile-associated disease"/>
</observation>
```