



Florida Department of Health

Bureau of Epidemiology

Guide to Importing Data Into the National Healthcare Safety Network: Procedure Denominator Report

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Version Control

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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 Procedure Denominator Report (PDR) reports 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 [Procedure Denominator XML 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.
- CDC Release 5 document: [HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection \(HAI\) Reports; Release 5](#).

- Example of a Procedure Denominator Report CDA file at ([Procedure Denominator XML 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 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 that may arise 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 FDOH HAI website. 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.
- Tables referenced 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 the HAI rates.
- Unlike other denominator reports which are a summary of the monthly patient information, the Procedure Denominator Report (PDR) is the data for a single-patient. A PDR should be entered into NHSN based on the facility's selected group of procedures for surveillance during the month. All the PDRs entered for the month are then used as the denominator when calculating the SSI Rate.
- PDR files must be entered prior to trying to import SSI reports.
- When importing SSI reports, the NHSN system will attempt to link each SSI with a PDR. Using the unique procedure identifier that is assigned to each PDR and is also used in the SSI report, the NHSN system will link the SSI with a PDR. When a SSI and PDR report both contain the same unique procedure identifier the NHSN system will make the link automatically when SSI reports are being imported.

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)

Immunocompromised Observation
[observation: templateId 2.16.840.1.113883.10.20.5.6.19]

[description of the template]

1. **SHALL** contain [1..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2348)
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2349)
3. **SHALL** contain [1..1] code/@code="ASSERTION" Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2350)
4. **SHALL** contain [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2351)
5. **SHALL** contain [1..1] value/@code="370388006" Patient immunocompromized (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2352)

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 <code>setIds</code>	2.16.840.1.113883.3.117.1.1.5.2.1.1.1
its document IDs	2.16.840.1.113883.3.117.1.1.5.2.1.1.2
its 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 Procedure Denominator Report (PDR). 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
Infection-type Reports	
Procedure Denominator Report (...20.5.22)	Infection Risk Factors (Procedure) Section (...20.5.5.22) <ul style="list-style-type: none"> • Procedure Risk Factors Clinical Statement (Procedure Report) (...20.5.6.68) * <ul style="list-style-type: none"> ○ Wound Class Observation (...20.5.2.1.2) ○ Endoscope Used Clinical Statement (...20.5.2.1.3) • ASA (American Society of Anesthesiologists) Class Observation (...20.5.2.2.7.4) • Trauma Observation (...20.5.2.2.7.5) <p><i>(If procedure = spinal fusion or refusion)</i></p> <ul style="list-style-type: none"> • Diabetes Mellitus Observation (...20.5.2.2.7.7) <p><i>(If procedure = Cesarean)</i></p> <ul style="list-style-type: none"> • Height Observation (...20.5.2.2.7.9) • Weight Observation (...20.5.2.2.7.10) • Duration of Labor Observation (...20.5.2.2.7.11) • Estimated Maternal Blood Loss Observation (...20.5.2.2.7.12) Procedure Details Section (...20.5.5.14) <ul style="list-style-type: none"> • Procedure Details Clinical Statement in a Procedure Report (...20.5.6.33)** <ul style="list-style-type: none"> ○ Anesthesia Administration (...20.5.2.2.7.3) ○ Implant Observation (...20.5.6.20) ○ Non-autologous Transplant Observation (...20.5.6.25) <p><i>(If procedure = fusion/refusion)</i></p> Spinal Fusion Level Observation (...20.5.2.2.7.8)

* Whether the procedure was an emergency is recorded in a `methodCode` element. Whether the patient was an outpatient is recorded in the CDA Header in a Procedure Report.

** Hip or Knee Replacement Type is recorded in a `methodCode` element. Spinal Fusion Approach is recorded in an `approachSiteCode` element

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. These constraints are common to all HAI reports.

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>
  ...
</Clinical Document
```

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 Legal Authenticator)

The author may be software or may be a person in the role of infection control professional (ICP) is 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 [Procedure Denominator XML 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.

5. Generic Constraints for Procedure Denominator Report

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

Once entered into NHSN, the procedure reports are used as the denominator when calculating the SSI rate. It is worth noting again that Numerator and Denominator reports are two separate reports and therefore two separate CDA files. These two reports stand on their own but both reports are required for calculating the HAI rates. The PDR contains records for all procedures that have been selected for surveillance during a reporting month, regardless of whether or not an infection results. Hence, the facility will be submitting two different reports related to procedures where an infection has resulted. The PDR will contain the data about the procedure and the Surgical Site Infection (SSI) will contain data about the resulting infection.

5.1 Common Header Constraints

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

5.2 (3.8 HAI Procedure Denominator Report)

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.5.22]

The Procedure Denominator Report records a procedure performed for a single-person. The preferred title is “Denominator for Procedure Report.”

The date of the procedure is recorded as the *effectiveTime* in the Procedure Details Clinical Statement in a Procedure Report (*templateId* 2.16.840.1.113883.10.20.5.6.33).

The SSI Report and Procedure Report headers record, in *encompassingEncounter/code*, whether the patient was an outpatient.

NHSN uses the procedure ID, which is recorded in the Procedure Details Section, to establish a link between Procedure and SSI Reports.

1. Conforms to Header Constraints, HAI Single-person Reports Template (*templateId*: 2.16.840.1.113883.10.20.5.4.1).
2. **SHALL** contain [1..1] *componentOf/encompassingEncounter/code/@code*, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.1 *NHSNEncounterTypeCode* **STATIC** 20090130 (CONF:4484).

3. **SHALL NOT** contain [1..1]
`componentOf/encompassingEncounter/location/healthCareFacility/id/@extension` (CONF:4485).
4. **SHALL NOT** contain [1..1]
`componentOf/encompassingEncounter/location/healthCareFacility/code` (CONF:4486).
5. **SHALL** contain [1..1] `component/structuredBody` (CONF:4487).
 - a. This `component/structuredBody` **SHALL** contain [1..1] `component` (CONF:4488) such that it
 - i. **SHALL** contain [1..1] **Procedure Details Section in a Procedure Report**
 (templateId:2.16.840.1.113883.10.20.5.5.14)
 (CONF:4489).
 - b. This `component/structuredBody` **SHALL** contain [1..1] `component` (CONF:4490) such that it
 - i. **SHALL** contain [1..1] **Infection Risk Factors Section in a Procedure Report**
 (templateId:2.16.840.1.113883.10.20.5.5.22)
 (CONF:4491).

5.3 (4.1.5 Infection Risk Factors Section in a Procedure Report)

[section: templateId 2.16.840.1.113883.10.20.5.5.22]

The following table summarizes how the infection risk factors in a Procedure Report are represented.

Table 4 (Table 8: Requirements for Risk Factors Section in a Procedure Report)

Within an entry/procedure	As entry/observations
Emergency (as methodCode) Wound Class Endoscope	ASA Class Trauma <i>If spinal fusion or refusion:</i> Diabetes mellitus <i>If Cesarean:</i> Height Weight Labor duration Estimated blood loss

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:4475).
3. **SHALL** contain [1..1] `entry` (CONF:4476) such that it
 - a. **SHALL** contain [1..1] **Procedure Risk Factors Clinical Statement in a Procedure Report**

- (templateId:2.16.840.1.113883.10.20.5.6.68)
(CONF:4477).
4. **SHALL** contain [1..1] **entry** (CONF:4478) such that it
 - a. **SHALL** contain [1..1] **ASA Class Observation**
(templateId:2.16.840.1.113883.10.20.5.2.2.7.4)
(CONF:4479).
 5. **SHALL** contain [1..1] **entry** (CONF:4480) such that it
 - a. **SHALL** contain [1..1] **Trauma Observation**
(templateId:2.16.840.1.113883.10.20.5.2.2.7.5)
(CONF:4481).
 6. If the procedure, recorded in the Details Section of the report, was a Cesarean (code/@code is 2115-4), an entry element **SHALL** be present for each of the following: Height Observation (templateId 2.16.840.1.113883.10.20.5.2.2.7.9), Weight Observation (templateId 2.16.840.1.113883.10.20.5.2.2.7.10), Duration of Labor Observation (templateId 2.16.840.1.113883.10.20.5.2.2.7.11), and Blood Loss Observation (templateId 2.16.840.1.113883.10.20.5.2.2.7.12). (CONF:4482).
 7. If the procedure, recorded in the Details Section of the report, was a spinal fusion or refusion (code/@code is either 2137-8 or 2135-2), an entry element **SHALL** be present containing a Diabetes Mellitus Observation (templateId 2.16.840.1.113883.10.20.5.2.2.7.7). (CONF:4483).

Figure 10 (Figure 16: Risk factors section in a procedure report example)

```
<entry>
  <procedure classCode="PROC" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.5.6.68"/>
    <id root="2.16.840.1.113883.3.117.1.1.5.2.1.1.4" extension="92"/>
    <methodCode codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED"
      code="373110003"
      displayName="Emergency"/>
    <entryRelationship>
      <observation>
        <templateId root="2.16.840.1.113883.10.20.5.2.1.2"/>
        ...
      </observation>
    </entryRelationship>
    <entryRelationship>
      <procedure>
        <templateId root="2.16.840.1.113883.10.20.5.2.1.3"/>
        ...
      </procedure>
    </entryRelationship>
  </procedure>
</entry>
<entry>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.5.2.2.7.4"/>
    ...
  </observation>
</entry>
<entry>
  <observation>
    <templateId root="2.16.840.1.113883.10.20.5.2.2.7.5"/>
    ...
  </observation>
</entry>
```

5.4 (5.2.48 Procedure Risk Factors Clinical Statement in a Procedure Report)

[procedure: templateId 2.16.840.1.113883.10.20.5.6.68]

This clinical statement records the detail required in a Procedure Report about the circumstances in which a procedure was performed.

The value of the `id` element must be globally unique and in general need not be an ID used outside the document. Its function is to identify this procedure as being the same as the one documented in the Details Section of the same report.

1. **SHALL** contain [1..1] `@classCode="PROC"` Procedure (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:4464).
2. **SHALL** contain [1..1] `@moodCode="EVN"` Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:4465).
3. **SHALL** contain [1..1] `id` (CONF:4466).

4. The value of the `id` element **SHALL** be the same as the value of the corresponding `procedure/id` element in the Details Section of the report. (CONF:4467).
5. If the procedure was an emergency, the procedure element **SHALL** contain a `methodCode` element where the value of `@code` is 373110003 Emergency procedure 2.16.840.1.113883.6.96 SNOMED CT **STATIC**. (CONF:4468).
6. **SHALL** contain [1..1] `entryRelationship` (CONF:4469) such that it
 - a. **SHALL** contain [1..1] `@typeCode="COMP"` Has component (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:4470).
 - b. **SHALL** contain [1..1] `Wound Class Observation` (templateId:2.16.840.1.113883.10.20.5.2.1.2) (CONF:4471).
7. **SHALL** contain [1..1] `entryRelationship` (CONF:4472) such that it
 - a. **SHALL** contain [1..1] `@typeCode="COMP"` Has component (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:4473).
 - b. **SHALL** contain [1..1] `Endoscope Used Clinical Statement` (templateId:2.16.840.1.113883.10.20.5.2.1.3) (CONF:4474).

Figure 11 (Figure 76: Procedure risk factors example)

```

<procedure classCode="PROC" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.6.68"/>
  <id root="2.16.840.1.113883.3.117.1.1.5.2.1.1.4" extension="92"/>
  ...
</procedure>

```

5.5 (5.2.70 Wound Class Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.1.2]

NHSN patient safety protocol on this topic is an adaptation of (not a change to) the American College of Surgeons (ACoS) definitions, which are the definitions used by SNOMED. Thus, SNOMED wound-class codes are appropriate for use with this observation.

1. **SHALL** contain [1..1] `@classCode="OBS"` Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2474).
2. **SHALL** contain [1..1] `@moodCode="EVN"` Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2475).
3. **SHALL** contain [1..1] `code/@code="420089007"` CDC Wound Classification Category (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2477).
4. **SHALL** contain [1..1] `statusCode/@code="completed"` Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2478).
5. **SHALL** contain [1..1] `value` (CONF:2598).
6. If the wound classification is known, the value of `value/@code` **SHALL** be selected from Value Set 2.16.840.1.113883.13.9

NHSNWoundClassCode **STATIC** 20080130. If the wound classification is not known, the value of value/@nullFlavor **SHALL** be UNK. (CONF:2597).

Table 5 (Table 65: Wound Class Value Set)

Value Set: NHSNWoundClassCode 2.16.840.1.113883.13.9 Code System: SNOMED CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
418780004	SNOMED CT	Class I/Clean (Clean)
418115006	SNOMED CT	Class II/Clean Contaminated (Clean-contaminated)
419877002	SNOMED CT	Class III/Contaminated (Contaminated)
418422005	SNOMED CT	Class IV/Dirty Infected (Dirty)

Figure 12 (Figure 101: Wound class observation example)

```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.2.1.2" />
  <code codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    code="420089007"
    displayName="CDC Wound Classification Category" />
  <statusCode code="completed" />
  <value xsi:type="CD"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    code="418115006"
    displayName="Class II/Clean Contaminated" />
</observation>

If the wound class is unknown:

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.2.1.2" />
  <code codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    code="420089007"
    displayName="CDC Wound Classification Category" />
  <statusCode code="completed" />
  <value xsi:type="CD" nullFlavor="UNK" />
</observation>

```

5.6 (5.2.18 Endoscope Used Clinical Statement)

[procedure: templateId 2.16.840.1.113883.10.20.5.2.1.3]

This clinical statement records whether an endoscope was used.

If an endoscope was used, set the value of @negationInd to false. If an endoscope was not used, set the value of @negationInd to true.

1. **SHALL** contain [1..1] **@classCode="PROC"** Procedure (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2315).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2316).
3. **SHALL** contain **@negationInd** (CONF:2317).
4. **SHALL** contain [1..1] **code/@code="423827005"** Endoscopy (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2318).

Figure 13 (Figure 43: Endoscope used procedure example)

```

<procedure classCode="PROC" moodCode="EVN">
  ...
  <entryRelationship typeCode="COMP">
    <procedure classCode="PROC" moodCode="EVN" negationInd="false">
      <templateId root="2.16.840.1.113883.10.20.5.2.1.3"/>
      <code codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED"
        code="423827005"
        displayName="Endoscopy"/>
    </procedure>
  </entryRelationship>
  ...
</procedure>

```

5.7 (5.2.5 ASA Class Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.4]

This observation records the patient's physical status using the American Society of Anesthesiologists (ASA) Class Codes. The SNOMED CT representation of ASA Class Codes includes a sixth value (413500003 ASA physical status class 6 for brain-dead patients taken to the operating room to remove organs for transplant). This sixth value is not part of the value set allowed in a CDA document submitted to NHSN.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2292).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2293).
3. **SHALL** contain [1..1] **@negationInd="false"** (CONF:4219).
4. **SHALL** contain [1..1] **code/@code="ASSERTION"** Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2289).
5. **SHALL** contain [1..1] **statusCode/@code="completed"** Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2290).
6. **SHALL** contain [1..1] **value/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.10 NHSNASAClassCode **STATIC** 20080130 (CONF:2291).

Table 6 (Table 11: ASA Class Value Set)

Value Set: NHSNASAClassCode 2.16.840.1.113883.13.10 Code System: SNOMED CT 2.16.840.1.113883.6.96		
Code	Code System	Meaning
413495001	SNOMED CT	ASA physical status class 1 (Normally healthy patient)
413496000	SNOMED CT	ASA physical status class 2 (Patient with mild systemic disease)
413497009	SNOMED CT	ASA physical status class 3 (Patient with severe systemic disease, not incapacitating)
413498004	SNOMED CT	ASA physical status class 4 (Patient with incapacitating systemic disease, constant threat to life)
413499007	SNOMED CT	ASA physical status class 5 (Moribund patient, < 24-hour life expectancy)

Figure 14 (Figure 29: ASA class observation example)

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.4" />
  <code codeSystem="2.16.840.1.113883.5.4" code="ASSERTION" />
  <statusCode code="completed" />
  <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    value="413496000"
    displayName="Patient with mild systemic disease" />
</observation>
```

5.8 (5.2.65 Trauma Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.5]

This observation records whether the person had trauma. It is used in reporting the circumstances of a procedure.

If trauma was involved, set the value of @negationInd to false. If trauma 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:2450).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2451).
3. **SHALL** contain @negationInd (CONF:2452).
4. **SHALL** contain [1..1] code/@code="ASSERTION" Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2453).
5. **SHALL** contain [1..1] statusCode/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2454).
6. **SHALL** contain [1..1] value/@code="417746004" Trauma (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2455).

Figure 15 (Figure 96: Trauma observation example)

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.5"/>
  <code codeSystem="2.16.840.1.113883.5.4" code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
    code="417746004"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    displayName="Trauma"/>
</observation>
```

5.9 (5.2.14 Diabetes Mellitus Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.7]

This observation records whether the person had diabetes mellitus.

If the person did have diabetes, set the value of @negationInd to false. If the person did not have diabetes mellitus, 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:2299).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2300).
3. **SHALL** contain @negationInd (CONF:2301).
4. **SHALL** contain [1..1] code/@code="ASSERTION" Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2302).
5. **SHALL** contain [1..1] statusCode/@code="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2303).
6. **SHALL** contain [1..1] value/@code="73211009" Diabetes mellitus (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2304).

Figure 16 (Figure 39: Diabetes mellitus observation example)

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.7"/>
  <code code="ASSERTION"
    codeSystem="2.16.840.1.113883.5.4"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
    code="73211009"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    displayName="Diabetes mellitus"/>
</observation>
```

5.10 (5.2.23 Height Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.9]

This observation records a body height. NHSN protocol requires that the value be an integer.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2339).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2340).
3. **SHALL** contain [1..1] **@negationInd="false"** (CONF:4222).
4. **SHALL** contain [1..1] **code/@code="50373000"** Body height (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2341).
5. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2342).
6. **SHALL** contain [1..1] **value** (CONF:2343).
 - a. This value **SHALL** contain **@value** (CONF:2344).
 - b. This value **SHALL** contain **@unit** (CONF:2345).
7. The value of **value/@xsi:type** **SHALL** be **PQ**. (CONF:2603).
8. The value of **value/@value** **SHALL** be a non-negative real number representing the body height in terms of the units specified in **@unit**. (CONF:2346).

Figure 17 (Figure 48: Height observation example)

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.9"/>
  <code code="50373000"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    displayName="Body Height"/>
  <statusCode code="completed"/>
  <value xsi:type="PQ" value="190" unit="cm"/>
</observation>
```

5.11 (5.2.69 Weight Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.10]

This observation records a body weight. NHSN protocol requires that the value be an integer.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2482).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2483).
3. **SHALL** contain [1..1] **@negationInd="false"** (CONF:4220).
4. **SHALL** contain [1..1] **code/@code="27113001"** Body weight (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2484).
5. **SHALL** contain [1..1] **statusCode/@code="completed"** Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2485).
6. **SHALL** contain [1..1] **value** (CONF:2486).

- a. This value **SHALL** contain [1..1] **@xsi:type="PQ"** (CONF:4539).
7. The value of `value/@value` **SHALL** be a non-negative real number representing the body weight. (CONF:2488).

Figure 18 (Figure 100: Weight observation example)

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.10"/>
  <code code="27113001"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    displayName="Body weight"/>
  <statusCode code="completed"/>
  <value xsi:type="PQ" value="65" unit="kg"/>
</observation>
```

5.12 (5.2.16 Duration of Labor Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.11]

This observation records the duration of labor in `value/width`. NHSN protocol requires that the duration be expressed as an integer.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2305).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2306).
3. **SHALL** contain [1..1] **code/@code="289248003"** Duration of labor (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2308).
4. **SHALL** contain [1..1] **statusCode/@code="completed"** Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2309).
5. **SHALL** contain [1..1] **value** (CONF:2310).
 - a. This value **SHALL** contain [1..1] **@xsi:type="IVL_TS"** (CONF:4536).
 - b. This value **SHALL** contain [1..1] **width** (CONF:2311).
 - i. This width **SHALL** contain **@value** (CONF:2312).
 - ii. This width **SHALL** contain **@unit** (CONF:2313).
6. The value of `width/@value` **SHALL** be a non-negative real number representation the duration of labor in terms of the units specified in `@unit`. (CONF:2314).

Figure 19 (Figure 41: Duration of labor observation example)

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.11"/>
  <code code="289248003"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    displayName="Duration of labor"/>
  <statusCode code="completed"/>
  <value xsi:type="IVL_TS">
    <width value="8" unit="h"/>
  </value>
</observation>
```

5.13 (5.2.19 Estimated Maternal Blood Loss Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.12]

This observation records the estimated blood loss. NHSN protocol requires that the value be an integer.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2319).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2320).
3. **SHALL** contain [1..1] **@negationInd="false"** (CONF:4221).
4. **SHALL** contain [1..1] **code/@code="409086003"** Estimated maternal blood loss (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2321).
5. **SHALL** contain [1..1] **statusCode/@code="completed"** Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2322).
6. **SHALL** contain [1..1] **value** (CONF:2323).
 - a. This value **SHALL** contain [1..1] **@xsi:type="PQ"** (CONF:4538).
 - b. This value **SHALL** contain **@value** (CONF:2324).
 - c. This value **SHALL** contain **@unit** (CONF:2325).
7. The value of **value/@value** **SHALL** be a non-negative real number representing the estimated blood loss in terms of the units specified in **@unit**. (CONF:2326).

Figure 20 (Figure 44: Estimated maternal blood loss observation example)

```
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.12"/>
  <code code="409086003"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    displayName="Estimated maternal blood loss"/>
  <statusCode code="completed"/>
  <value xsi:type="PQ" value="250" unit="mL"/>
</observation>
```

5.14 (4.2.8 Procedure Details Section in a Procedure Report)

[section: templateId 2.16.840.1.113883.10.20.5.5.14]

Risk factors that are not aspects of the procedure itself are recorded in the Risk Factors Section.

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:2822).
3. **SHALL** contain [1..1] **entry** (CONF:2823).
 - a. This entry **SHALL** contain [1..1] **Procedure Details Clinical Statement in a Procedure Report** (templateId:2.16.840.1.113883.10.20.5.6.33) (CONF:2824).

5.15 (5.2.47.2 Procedure Details Clinical Statement in a Procedure Report)

[procedure: templateId 2.16.840.1.113883.10.20.5.6.33]

This clinical statement records the detail required in a Procedure Report about a procedure.

NHSN uses the procedure `id`, along with other data, to establish a link between a Procedure Report and an SSI Report; the value of the procedure `id` must be the same in both the report of a procedure and the report of a surgical-site infection resulting from that procedure.

1. **SHALL** contain [1..1] **@classCode="PROC"** Procedure (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2713).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2714).
3. **SHALL** contain [1..1] **id** (CONF:2715).
4. **SHALL** contain [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.13.17 NHSNProcedureCategoryCode **DYNAMIC** (CONF:2716).
5. **SHALL** contain [1..1] **effectiveTime** (CONF:2717).
 - a. This effectiveTime **SHALL** contain [1..1] **low** (CONF:2718).
 - b. This effectiveTime **SHALL** contain [1..1] **width** (CONF:3200).
6. **SHALL** contain [1..1] **entryRelationship** (CONF:2719) such that it
 - a. **SHALL** contain [1..1] **@typeCode="COMP"** Has component, which **SHALL** be selected from ValueSet (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:2720).
 - b. **SHALL** contain [1..1] **Anesthesia Administration Clinical Statement** (templateId:2.16.840.1.113883.10.20.5.2.2.7.3) (CONF:2721).
7. **SHALL** contain [1..1] **entryRelationship** (CONF:2722) such that it

- a. **SHALL** contain [1..1] **@typeCode="COMP"** Has component (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:2723).
 - b. **SHALL** contain [1..1] **Implant Observation** (templateId:2.16.840.1.113883.10.20.5.6.20) (CONF:2724).
8. **SHALL** contain [1..1] **entryRelationship** (CONF:2725) such that it
- a. **SHALL** contain [1..1] **@typeCode="COMP"** Has component (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:2726).
 - b. **SHALL** contain [1..1] **Non-autologous Transplant Observation** (templateId:2.16.840.1.113883.10.20.5.6.25) (CONF:2727).
9. If the procedure is a fusion or refusion (code/@code is either 2137-8 or 2135-2), an approachSiteCode element **SHALL** be present where the value of @code is selected from Value Set 2.16.840.1.113883.13.2 NHSNSpinalFusionApproachCode **STATIC** 20090625. (CONF:2728).
10. If the procedure is a fusion or refusion, an entryRelationship element where the value of @typeCode is COMP **SHALL** be present, containing a Spinal Fusion Level Observation (templateId 2.16.840.1.113883.10.20.5.2.2.7.8). (CONF:2729).
11. If the procedure category code represents a hip replacement, a methodCode element **SHALL** be present where the value of @code is selected from Value Set 2.16.840.1.113883.13.3 NHSNHipReplacementCode **STATIC** 20090625. (CONF:2730).
12. If the procedure category code represents a knee replacement, a methodCode element **SHALL** be present where the value of @code is selected from Value Set 2.16.840.1.113883.13.4 NHSNKneeReplacementCode **STATIC** 20090625. (CONF:2731).

Table 7 (Table 1: Spinal Fusion Approach Value Set)

Value Set: NHSNSpinalFusionApproachCode 2.16.840.1.113883.13.2 Code System: cdcNHSN 2.16.840.1.113883.6.277 or SNOMED CT 2.16.840.1.113883.6.96		
Code	Code System	Meaning
255549009	SNOMED CT	Anterior
255551008	SNOMED CT	Posterior
1205-4	cdcNHSN	anterior posterior
1210-4	cdcNHSN	lateral transverse

Figure 21 (Figure 2: Spinal fusion approach example)

```

<procedure classCode="PROC" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.6.33"/>
  <id root="2.16.840.1.113883.3.117.1.1.5.2.1.1.4" extension="92"/> ...
  <approachSiteCode codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    code="1205-4"
    displayName="anterior posterior"/>

  <entryRelationship typeCode="COMP">
    <observation>
      ...
    </observation>
  </entryRelationship>
  ...
</procedure>

```

Table 8 (Table 37: Hip Replacement Value Set)

Value Set: NHSNHipReplacementCode 2.16.840.1.113883.13.3		
Code System: cdcNHSN 2.16.840.1.113883.6.277		
Code	Code System	Meaning
1305-2	cdcNHSN	partial primary
1310-2	cdcNHSN	partial revision
1320-1	cdcNHSN	total primary
1315-1	cdcNHSN	total revision

Figure 22 (Figure 72: Hip replacement methodCode example)

```

<procedure>
  ...
  <methodCode codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    code="1320-1"
    displayName="total primary"/>
</procedure/>

```

Table 9 (Table 38: Knee Replacement Value Set)

Value Set: NHSNKneeReplacementCode 2.16.840.1.113883.13.4		
Code System: cdcNHSN 2.16.840.1.113883.6.277		
Code	Code System	Meaning
1410-0	cdcNHSN	primary (total)
1405-0	cdcNHSN	revision (total or partial)

Figure 23 (Figure 73: Knee replacement methodCode example)

```
<procedure>
...
  <methodCode codeSystem="2.16.840.1.113883.6.277"
              codeSystemName="cdcNHSN"
              code="1410-0"
              displayName="total primary"/>
</procedure>
```

5.16 (5.2.4 Anesthesia Administration Clinical Statement)

[substanceAdministration: templateId
2.16.840.1.113883.10.20.5.2.2.7.3]

This clinical statement reports whether anesthesia was administered.

If anesthesia was not administered, set the value of @negationInd to true. If anesthesia was administered, set the value of @negationInd to false.

1. **SHALL** contain [1..1] @classCode="SBADM" Substance administration (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2234).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2235).
3. **SHALL** contain @negationInd (CONF:2238).
4. **SHALL** contain [1..1] consumable/manufacturedProduct/manufacturedLabeledDrug (CONF:2236).
 - a. This consumable/manufacturedProduct/manufacturedLabeledDrug **SHALL** contain [1..1] code/@code="84451006" General Anesthesia (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2237).

Figure 24 (Figure 28: Anesthesia administration example)

```
<procedure classCode="PROC" moodCode="EVN">
...
  <entryRelationship typeCode="COMP">
    <substanceAdministration classCode="SBADM" moodCode="EVN"
                            negationInd="false">
      <templateId root="2.16.840.1.113883.10.20.5.2.2.7.3"/>
      <consumable>
        <manufacturedProduct>
          <manufacturedLabeledDrug>
            <code code="84451006"
                  codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED"
                  displayName="general anesthesia"/>
          </manufacturedLabeledDrug>
        </manufacturedProduct>
      </consumable>
    </substanceAdministration>
  </entryRelationship>
</procedure>
```

5.17 (5.2.28 Implant Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.6.20]

The Implant Observation records whether the procedure being reported included an implant.

If an implant was used in the procedure, set the value of @negationInd to false. If an implant was not used in the procedure, 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:2353).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2354).
3. **SHALL** contain @negationInd (CONF:2355).
4. **SHALL** contain [1..1] code/@code="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2356).
5. **SHALL** contain [1..1] statusCode/@code="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2357).
6. **SHALL** contain [1..1] value/@code="71861002" Implantation (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) **STATIC** (CONF:2358).

Figure 25 (Figure 54: Implant observation example)

```
<!-- patient did have implant -->
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.6.20"/>
  <code codeSystem="2.16.840.1.113883.5.4"
        code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
        code="71861002"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED"
        displayName="Implantation"/>
</observation>
```

5.18 (5.2.36 Non-autologous Transplant Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.6.25]

This observation records whether a transplant was autologous or non-autologous.

If a non-autologous transplant occurred, set the value of @negationInd to false. If a non-autologous transplant did not occur, 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:2365).
2. **SHALL** contain [1..1] @moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2366).
3. **SHALL** contain @negationInd (CONF:2367).

4. **SHALL** contain [1..1] **code/@code="ASSERTION"** (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2368).
5. **SHALL** contain [1..1] **statusCode/@code="completed"** (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2369).
6. **SHALL** contain [1..1] **value/@code="3189-8"** Non-autologous transplant (CodeSystem: 2.16.840.1.113883.6.277 cdcNHSN) **STATIC** (CONF:2370).

Figure 26 (Figure 62: Non-autologous transplant observation example)

```

<!-- Patient had a Non-Autologous transplant -->
<observation classCode="OBS" moodCode="EVN" negationInd="false">
  <templateId root="2.16.840.1.113883.10.20.5.6.25"/>
  <code codeSystem="2.16.840.1.113883.5.4" code="ASSERTION"/>
  <statusCode code="completed"/>
  <value xsi:type="CD"
    code="3189-8"
    codeSystem="2.16.840.1.113883.6.277"
    codeSystemName="cdcNHSN"
    displayName="Non-autologous transplant"/>
</observation>

```

5.19 (5.2.61 Spinal Fusion Level Observation)

[observation: templateId 2.16.840.1.113883.10.20.5.2.2.7.8]

This observation records the spinal level of a spinal fusion procedure.

1. **SHALL** contain [1..1] **@classCode="OBS"** Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:2433).
2. **SHALL** contain [1..1] **@moodCode="EVN"** Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:2434).
3. **SHALL** contain [1..1] **code/@code="ASSERTION"** Assertion (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:2436).
4. **SHALL** contain [1..1] **statusCode/@code="completed"** Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:2437).
5. **SHALL** contain [1..1] **value** (CONF:2438).
6. The value of **value/@xsi:type** **SHALL** be CD. (CONF:2613).
7. If the spinal fusion level is known, the value of **value/@code** **SHALL** be selected from Value Set 2.16.840.1.113883.13.11 NHSNSpinalFusionLevelCode **STATIC** 20090625. If the spinal fusion level is not known, the value of **value/@nullFlavor** **SHALL** be NI. (CONF:2439).

Table 10 (Table 50: Spinal Fusion Level Value Set)

Value Set: NHSNSpinalFusionLevelCode 2.16.840.1.113883.13.11 Code System: cdcNHSN 2.16.840.1.113883.6.277		
Code	Code System	Print Name
1101-5	cdcNHSN	atlas-axis (C1-C2 only)
1102-3	cdcNHSN	atlas-axis/cervical (C1-C7: any combination)
1103-1	cdcNHSN	cervical (C3-C7: any combination)
1104-9	cdcNHSN	cervical/dorsal/dorsolumbar (Extends from any cervical through any lumbar levels)
1105-6	cdcNHSN	dorsal/dorsolumbar (T1-L5: any combination)
1106-4	cdcNHSN	lumbar/lumbosacral (L1-S5: any combination)

Figure 9 (Figure 89: Spinal fusion level observation example)

```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.5.2.2.7.8" />
  <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="1101-5"
    displayName="Spinal Fusion of Atlas-Axis" />
</observation>

```