

3.105.1 Allergy - Intolerance Observation (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.7:2014-06-09
(open)]

Table 496: Allergy - Intolerance Observation (V2) Contexts

Contained By:	Contains:
Health Concern Act (V2) (optional) Risk Concern Act (V2) (optional) Allergy Concern Act (V3) (required)	Reaction Observation (V2) (optional) Severity Observation (V2) (optional) Author Participation (optional) Criticality Observation (optional) Allergy Status Observation (optional)

This template reflects a discrete observation about a patient's allergy or intolerance. Because it is a discrete observation, it will have a statusCode of "completed". The effectiveTime, also referred to as the "biologically relevant time" is the time at which the observation holds for the patient. For a provider seeing a patient in the clinic today, observing a history of penicillin allergy that developed five years ago, the effectiveTime is five years ago.

The effectiveTime of the Allergy - Intolerance Observation is the definitive indication of whether or not the underlying allergy/intolerance is resolved. If known to be resolved, then an effectiveTime/high would be present. If the date of resolution is not known, then effectiveTime/high will be present with a nullFlavor of "UNK".

The agent responsible for an allergy or adverse reaction is not always a manufactured material (for example, food allergies), nor is it necessarily consumed. The following constraints reflect limitations in the base CDA R2 specification, and should be used to represent any type of responsible agent, i.e., use playingEntity classCode = "MMAT" for all agents, manufactured or not.

Table 497: Allergy - Intolerance Observation (V2) Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.7:2014-06-09)					
@classCode	1..1	SHALL		1098-7379	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		1098-7380	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
@negationInd	0..1	MAY		1098-31526	
templateId	1..1	SHALL		1098-7381	
@root	1..1	SHALL		1098-10488	2.16.840.1.113883.10.20.22.4.7
@extension	1..1	SHALL		1098-32526	2014-06-09
id	1..*	SHALL		1098-7382	
code	1..1	SHALL		1098-15947	
@code	1..1	SHALL		1098-15948	ASSERTION
@codeSystem	1..1	SHALL		1098-32153	urn:oid:2.16.840.1.113883.5.4 (HL7ActCode) = 2.16.840.1.113883.5.4
statusCode	1..1	SHALL		1098-19084	
@code	1..1	SHALL		1098-19085	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
effectiveTime	1..1	SHALL		1098-7387	
low	1..1	SHALL		1098-31538	
high	0..1	MAY		1098-31539	
value	1..1	SHALL	CD	1098-7390	urn:oid:2.16.840.1.113883.3.88.12.3221.6.2 (Allergy and Intolerance Type)
author	0..*	SHOULD		1098-31143	Author Participation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119)
participant	1..1	SHALL		1098-7402	
@typeCode	1..1	SHALL		1098-7403	urn:oid:2.16.840.1.113883.5.90 (HL7ParticipationType) = CSM
participantRole	1..1	SHALL		1098-	

XPath	Card.	Verb	Data Type	CONF#	Value
				7404	
@classCode	1..1	SHALL		1098-7405	urn:oid:2.16.840.1.113883.5.110 (HL7RoleClass) = MANU
playingEntity	1..1	SHALL		1098-7406	
@classCode	1..1	SHALL		1098-7407	urn:oid:2.16.840.1.113883.5.41 (HL7EntityClass) = MMAT
code	1..1	SHALL		1098-7419	urn:oid:2.16.840.1.113762.1.4.1010.1 (Substance Reactant for Intolerance)
entryRelationship	0..1	MAY		1098-32939	
@typeCode	1..1	SHALL		1098-32940	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
@inversionInd	1..1	SHALL		1098-32941	true
observation	1..1	SHALL		1098-32942	Allergy Status Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.28:2019-06-20)
entryRelationship	0..1	SHOULD NOT		1098-9961	
@typeCode	1..1	SHALL		1098-9962	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
@inversionInd	1..1	SHALL		1098-9964	true
observation	1..1	SHALL		1098-15956	Severity Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.8:2014-06-09)
entryRelationship	0..*	SHOULD		1098-7447	
@typeCode	1..1	SHALL		1098-7907	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = MFST
@inversionInd	1..1	SHALL		1098-7449	true
observation	1..1	SHALL		1098-15955	Reaction Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.9:2014-06-09)
entryRelationship	0..1	SHOULD		1098-32910	
@typeCode	1..1	SHALL		1098-32911	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ

XPath	Card.	Verb	Data Type	CONF#	Value
@inversionInd	1..1	SHALL		1098-32912	true
observation	1..1	SHALL		1098-32913	Criticality Observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.145)

1. Conforms to [Substance or Device Allergy - Intolerance Observation \(V2\)](#) template (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.3.90:2014-06-09).
2. **SHALL** contain exactly one [1..1] **@classCode="OBS"** Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:1098-7379).
3. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:1098-7380).
4. **MAY** contain zero or one [0..1] **@negationInd** (CONF:1098-31526).
Note: Use negationInd="true" to indicate that the allergy was not observed.
5. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-7381) such that it
 - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.4.7"** (CONF:1098-10488).
 - b. **SHALL** contain exactly one [1..1] **@extension="2014-06-09"** (CONF:1098-32526).
6. **SHALL** contain at least one [1..*] **id** (CONF:1098-7382).
7. **SHALL** contain exactly one [1..1] **code** (CONF:1098-15947).
 - a. This code **SHALL** contain exactly one [1..1] **@code="ASSERTION"** Assertion (CONF:1098-15948).
 - b. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.5.4"** (CodeSystem: HL7ActCode urn:oid:2.16.840.1.113883.5.4) (CONF:1098-32153).
8. **SHALL** contain exactly one [1..1] **statusCode** (CONF:1098-19084).
 - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14 **STATIC**) (CONF:1098-19085).
9. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:1098-7387).
Note: If the allergy/intolerance is known to be resolved, but the date of resolution is not known, then the high element SHALL be present, and the nullFlavor attribute SHALL be set to 'UNK'.
 - a. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:1098-31538).
Note: The effectiveTime/low (a.k.a. "onset date") asserts when the allergy/intolerance became biologically active.
 - b. This effectiveTime **MAY** contain zero or one [0..1] **high** (CONF:1098-31539).
Note: The effectiveTime/high (a.k.a. "resolution date") asserts when the allergy/intolerance became biologically resolved.
10. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet [Allergy and Intolerance Type](#) urn:oid:2.16.840.1.113883.3.88.12.3221.6.2 **DYNAMIC** (CONF:1098-7390).
Note: The consumable participant points to the precise allergen or substance of intolerance.

Because the consumable and the reaction are more clinically relevant than a categorization of the allergy/adverse event type, many systems will simply assign a fixed value here (e.g., "allergy to substance").

11. **SHOULD** contain zero or more [0..*] [Author Participation](#) (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119) (CONF:1098-31143).
12. **SHALL** contain exactly one [1..1] **participant** (CONF:1098-7402) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode**="CSM" Consumable (CodeSystem: HL7ParticipationType urn:oid:2.16.840.1.113883.5.90 **STATIC**) (CONF:1098-7403).
 - b. **SHALL** contain exactly one [1..1] **participantRole** (CONF:1098-7404).
 - i. This participantRole **SHALL** contain exactly one [1..1] **@classCode**="MANU" Manufactured Product (CodeSystem: HL7RoleClass urn:oid:2.16.840.1.113883.5.110 **STATIC**) (CONF:1098-7405).
 - ii. This participantRole **SHALL** contain exactly one [1..1] **playingEntity** (CONF:1098-7406).
 1. This playingEntity **SHALL** contain exactly one [1..1] **@classCode**="MMAT" Manufactured Material (CodeSystem: HL7EntityClass urn:oid:2.16.840.1.113883.5.41 **STATIC**) (CONF:1098-7407).
 2. This playingEntity **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet [Substance Reactant for Intolerance](#) urn:oid:2.16.840.1.113762.1.4.1010.1 **DYNAMIC** (CONF:1098-7419).
13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1098-32939) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002) (CONF:1098-32940).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" True (CONF:1098-32941).
 - c. **SHALL** contain exactly one [1..1] [Allergy Status Observation](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.28:2019-06-20) (CONF:1098-32942).
14. **SHOULD NOT** contain zero or one [0..1] **entryRelationship** (CONF:1098-9961) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002 **STATIC**) (CONF:1098-9962).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" True (CONF:1098-9964).
 - c. **SHALL** contain exactly one [1..1] [Severity Observation \(V2\)](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.8:2014-06-09) (CONF:1098-15956).
15. **SHOULD** contain zero or more [0..*] **entryRelationship** (CONF:1098-7447) such that it
 - a. **SHALL** contain exactly one [1..1] **@typeCode**="MFST" Is Manifestation of (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002 **STATIC**) (CONF:1098-7907).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" True (CONF:1098-7449).

- c. **SHALL** contain exactly one [1..1] [Reaction Observation \(V2\)](#) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.9:2014-06-09) (CONF:1098-15955).
16. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:1098-32910) such that it
- a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has Subject (CodeSystem: HL7ActRelationshipType urn:oid:2.16.840.1.113883.5.1002) (CONF:1098-32911).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:1098-32912).
 - c. **SHALL** contain exactly one [1..1] [Criticality Observation](#) (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.145) (CONF:1098-32913).

Figure 225: Allergy - Intolerance Observation (V2) Example

```
<observation classCode="OBS" moodCode="EVN">
  <!-- ** Allergy observation ** -->
  <templateId root="2.16.840.1.113883.10.20.22.4.7" extension="2014-06-09" />
  <id root="901db0f8-9355-4794-81cd-fd951ef07917" />
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
  <!-- Observation statusCode represents the status of the act of observing -->
  <statusCode code="completed" />
  <effectiveTime>
    <!-- The low value reflects the date of onset of the allergy -->
    <low nullFlavor="UNK" />
    <!-- The high value reflects when the allergy was known to be resolved
        (and will generally be absent) -->
  </effectiveTime>
  <value xsi:type="CD" code="419199007" displayName="Allergy to substance"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" />
  <author>
    <time value="201010110915-0800" />
    <assignedAuthor>
      <id extension="222223333" root="1.1.1.1.1.1.3" />
    </assignedAuthor>
  </author>
  <participant typeCode="CSM">
    <participantRole classCode="MANU">
      <playingEntity classCode="MMAT">
        <code code="2670" displayName="Codeine" codeSystem="2.16.840.1.113883.6.88"
codeSystemName="RxNorm" />
      </playingEntity>
    </participantRole>
  </participant>
  <entryRelationship typeCode="MFST" inversionInd="true">
    <observation classCode="OBS" moodCode="EVN">
      <!-- ** Reaction observation ** -->
      <templateId root="2.16.840.1.113883.10.20.22.4.9" extension="2014-06-09" />
      <id root="38c63dea-1a43-4f84-ab71-1ffd04f6aldd" />
      <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
      <text>
        <reference value="#reaction2" />
      </text>
      <statusCode code="completed" />
      <effectiveTime>
        <low nullFlavor="UNK" />
      </effectiveTime>
      <value xsi:type="CD" code="56018004" displayName="Wheezing"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" />
    </observation>
  </entryRelationship>
  <entryRelationship typeCode="SUBJ" inversionInd="true">
    <observation classCode="OBS" moodCode="EVN">
      <!-- ** Severity observation ** -->
      <templateId root="2.16.840.1.113883.10.20.22.4.8" extension="2014-06-09" />
      <code code="SEV" displayName="Severity Observation"
codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode" />
      <text>
        <reference value="#allergyseverity2" />
      </text>
      <statusCode code="completed" />
    </observation>
  </entryRelationship>
</observation>
```

```

        <value xsi:type="CD" code="255604002" displayName="Mild"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" />
    </observation>
</entryRelationship>
</observation>

```

3.106 Text Observation

[observation: identifier urn:oid:2.16.840.1.113883.10.20.6.2.12 (open)]

Table 498: Text Observation Contexts

Contained By:	Contains:
Diagnostic Imaging Report (V3) (optional)	SOP Instance Observation (optional) Quantity Measurement Observation (optional)

DICOM Template 2000 specifies that Imaging Report Elements of Value Type Text are contained in sections. The Imaging Report Elements are inferred from Basic Diagnostic Imaging Report Observations that consist of image references and measurements (linear, area, volume, and numeric). Text DICOM Imaging Report Elements in this context are mapped to CDA text observations that are section components and are related to the SOP Instance Observations (templateId 2.16.840.1.113883.10.20.6.2.8) or Quantity Measurement Observations (templateId 2.16.840.1.113883.10.20.6.2.14) by the SPRT (Support) act relationship.

A Text Observation is required if the findings in the section text are represented as inferred from SOP Instance Observations.