

7. **MAY** contain zero or one [0..1] **effectiveTime** (CONF:1098-31509).

Figure 225: Substance Administered Act Example

```
<substanceAdministration classCode="SBADM" moodCode="EVN">
  ...
  <consumable>
    ...
    <code code="43" codeSystem="2.16.840.1.113883.12.292" displayName="Hepatitis B
Vaccine" codeSystemName="CVX" />
  </consumable>
  <entryRelationship typeCode="COMP">
    <!-- This entryRelationship sequenceNumber indicates this is #2 in the series -->
    <sequenceNumber value="2" />
    <act classCode="ACT" moodCode="EVN">
      <!-- Substance Administered Act Template -->
      <templateId root="2.16.840.1.113883.10.20.22.4.118" />
      <id root="df8908d0-40f2-11e3-aa6e-0800200c9a66" />
      <code code="416118004" displayName="administration"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT" />
      <statusCode code="completed" />
      <effectiveTime value="19991101" />
    </act>
  </entryRelationship>
  ...
</substanceAdministration>
```

3.105 Substance or Device Allergy - Intolerance Observation (V2)

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.24.3.90:2014-06-09
(open)]

Table 492: Substance or Device Allergy - Intolerance Observation (V2) Contexts

Contained By:	Contains:
Health Concern Act (V2) (optional) Risk Concern Act (V2) (optional)	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 to a substance or device. Because it is a discrete observation, it will have a statusCode of "completed". The effectiveTime, also referred to as the 'clinically 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 Substance or Device 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".

Table 493: Substance or Device Allergy - Intolerance Observation (V2) Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.24.3.90:2014-06-09)					
@classCode	1..1	SHALL		1098-16303	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		1098-16304	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		1098-16305	
@root	1..1	SHALL		1098-16306	2.16.840.1.113883.10.20.24.3.90
@extension	1..1	SHALL		1098-32527	2014-06-09
id	1..*	SHALL		1098-16307	
code	1..1	SHALL		1098-16345	
@code	1..1	SHALL		1098-16346	ASSERTION
@codeSystem	1..1	SHALL		1098-32171	urn:oid:2.16.840.1.113883.5.4 (HL7ActCode) = 2.16.840.1.113883.5.4
statusCode	1..1	SHALL		1098-16308	
@code	1..1	SHALL		1098-26354	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
effectiveTime	1..1	SHALL		1098-16309	
low	1..1	SHALL		1098-31536	
high	0..1	MAY		1098-31537	
value	1..1	SHALL	CD	1098-16312	
@code	1..1	SHALL	CS	1098-16317	urn:oid:2.16.840.1.113883.3.88.12.3221.6.2 (Allergy and Intolerance Type)
author	0..*	SHOULD		1098-31144	Author Participation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119)
participant	0..*	SHOULD		1098-16318	
@typeCode	1..1	SHALL		1098-16319	urn:oid:2.16.840.1.113883.5.90 (HL7ParticipationType) = CSM

XPath	Card.	Verb	Data Type	CONF#	Value
participantRole	1..1	SHALL		1098-16320	
@classCode	1..1	SHALL		1098-16321	urn:oid:2.16.840.1.113883.5.110 (HL7RoleClass) = MANU
playingEntity	1..1	SHALL		1098-16322	
@classCode	1..1	SHALL		1098-16323	urn:oid:2.16.840.1.113883.5.41 (HL7EntityClass) = MMAT
code	1..1	SHALL		1098-16324	urn:oid:2.16.840.1.113762.1.4.1010.1 (Substance Reactant for Intolerance)
entryRelationship	0..1	MAY		1098-16333	
@typeCode	1..1	SHALL		1098-16335	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
@inversionInd	1..1	SHALL		1098-16334	true
observation	1..1	SHALL		1098-16336	Allergy Status Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.28:2019-06-20)
entryRelationship	0..*	SHOULD		1098-16337	
@typeCode	1..1	SHALL		1098-16339	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = MFST
@inversionInd	1..1	SHALL		1098-16338	true
observation	1..1	SHALL		1098-16340	Reaction Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.9:2014-06-09)
entryRelationship	0..1	SHOULD NOT		1098-16341	
@typeCode	1..1	SHALL		1098-16342	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
@inversionInd	1..1	SHALL		1098-16343	true
observation	1..1	SHALL		1098-16344	Severity Observation (V2) (identifier: urn:hl7ii:2.16.840.1.113883.10.20.22.4.8:2014-06-09)
entryRelationship	0..1	SHOULD		1098-32935	

XPath	Card.	Verb	Data Type	CONF#	Value
@typeCode	1..1	SHALL		1098-32936	urn:oid:2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
@inversionInd	1..1	SHALL		1098-32937	true
observation	1..1	SHALL		1098-32938	Criticality Observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.145)

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:1098-16303).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:1098-16304).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:1098-16305) such that it
 - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.24.3.90" (CONF:1098-16306).
 - b. **SHALL** contain exactly one [1..1] **@extension**="2014-06-09" (CONF:1098-32527).
4. **SHALL** contain at least one [1..*] **id** (CONF:1098-16307).
5. **SHALL** contain exactly one [1..1] **code** (CONF:1098-16345).
 - a. This code **SHALL** contain exactly one [1..1] **@code**="ASSERTION" Assertion (CONF:1098-16346).
 - 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:1098-32171).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:1098-16308).
 - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:1098-26354).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:1098-16309).
 Note: The effectiveTime/low (a.k.a. "onset date") asserts when the allergy/intolerance became clinically active. The effectiveTime/high (a.k.a. "resolution date") asserts when the allergy/intolerance became clinically resolved. 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:1098-31536).
 - b. This effectiveTime **MAY** contain zero or one [0..1] **high** (CONF:1098-31537).
8. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD" (CONF:1098-16312).
 - a. This value **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet [Allergy and Intolerance Type](#) urn:oid:2.16.840.1.113883.3.88.12.3221.6.2 **DYNAMIC** (CONF:1098-16317).
 Note: Many systems will simply assign a fixed value here (e.g., "allergy to substance").

9. **SHOULD** contain zero or more [0..*] [Author Participation](#) (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.119) (CONF:1098-31144).
10. **SHOULD** contain zero or more [0..*] **participant** (CONF:1098-16318) 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:1098-16319).
 - b. **SHALL** contain exactly one [1..1] **participantRole** (CONF:1098-16320).
 - 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:1098-16321).
 - ii. This participantRole **SHALL** contain exactly one [1..1] **playingEntity** (CONF:1098-16322).
 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:1098-16323).
 2. This playingEntity **SHALL** contain exactly one [1..1] **code**, which **MAY** be selected from ValueSet [Substance Reactant for Intolerance](#) urn:oid:2.16.840.1.113762.1.4.1010.1 **DYNAMIC** (CONF:1098-16324).
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:1098-16333) 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:1098-16335).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:1098-16334).
 - 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:1098-16336).
12. **SHOULD** contain zero or more [0..*] **entryRelationship** (CONF:1098-16337) 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:1098-16339).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:1098-16338).
 - 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:1098-16340).
13. **SHOULD NOT** contain zero or one [0..1] **entryRelationship** (CONF:1098-16341) 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:1098-16342).
 - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:1098-16343).
 - 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:1098-16344).
14. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:1098-32935) 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:1098-32936).
- b. **SHALL** contain exactly one [1..1] @inversionInd="true" True (CONF:1098-32937).
- c. **SHALL** contain exactly one [1..1] Criticality Observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.145) (CONF:1098-32938).

Table 494: Allergy and Intolerance Type

Value Set: Allergy and Intolerance Type urn:oid:2.16.840.1.113883.3.88.12.3221.6.2 (Clinical Focus: The class of substance and intolerance suffered by the patient),(Data Element Scope: Describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives)),(Inclusion Criteria:),(Exclusion Criteria:) This value set was imported on 6/24/2019 with a version of 20190319. Value Set Source: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113883.3.88.12.3221.6.2/expansion			
Code	Code System	Code System OID	Print Name
235719002	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Intolerance to food (finding)
414285001	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Allergy to food (finding)
416098002	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Allergy to drug (finding)
418038007	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Propensity to adverse reactions to substance (finding)
418471000	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Propensity to adverse reactions to food (disorder)
419199007	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Allergy to substance (finding)
419511003	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Propensity to adverse reactions to drug (finding)
420134006	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Propensity to adverse reaction (finding)
59037007	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Intolerance to drug (finding)

Table 495: Substance Reactant for Intolerance

<p>Value Set: Substance Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1</p> <p>(Clinical Focus: A substance or other type of agent (eg. Sunshine) that may be associated with an intolerance reaction event or a propensity to such an event. These concepts are expected to be at a more general level of abstraction (ingredients versus more specific formulations). This value set is quite general and includes concepts that may never cause an adverse event, particularly the included SNOMED CT concepts. This code system-specific value sets in this grouping value set are intended to provide broad coverage of all kinds of agents, but the expectation for use is that the chosen concept identifier for a substance should be appropriately specific and drawn from the available code systems in the following priority order: NDFRT, then RXNORM, then UNII, then SNOMEDCT. UNII is not included in the initial version. This overarching grouping value set is intended to support identification of drug classes, individual medication ingredients, foods, general substances and environmental entities.),(Data Element Scope: substance elements),(Inclusion Criteria: Any concept that could at some point cause an allergy or intolerance. Intended to include following value sets: Medication Clinical Drug (RxNorm), Clinical Drug Class (NDF-RT), Substance Other Than Clinical Drug (SNOMED CT). It was originally to also include all UNII codes but this will not be included initially.),(Exclusion Criteria: non-substance)</p> <p>This value set was imported on 6/29/2019 with a version of 20190620.</p> <p>Value Set Source: https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1010.1/expansion</p>			
Code	Code System	Code System OID	Print Name
1000082	RxNorm	urn:oid:2.16.840.1.113883.6.88	alcaftadine
1000086	RxNorm	urn:oid:2.16.840.1.113883.6.88	Lastacraft
1000104	RxNorm	urn:oid:2.16.840.1.113883.6.88	incobotulinumtoxinA
1000108	RxNorm	urn:oid:2.16.840.1.113883.6.88	Xeomin
1000112	RxNorm	urn:oid:2.16.840.1.113883.6.88	medroxyprogesterone acetate
1000146	RxNorm	urn:oid:2.16.840.1.113883.6.88	estradiol cypionate
1000492	RxNorm	urn:oid:2.16.840.1.113883.6.88	resveratrol
1000577	RxNorm	urn:oid:2.16.840.1.113883.6.88	microcrystalline cellulose
1000581	RxNorm	urn:oid:2.16.840.1.113883.6.88	Trichlorfon
1000705	RxNorm	urn:oid:2.16.840.1.113883.6.88	Benzalkonium / Tolnaftate
...			

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 "clinically 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	