

Implementation Guide for CDA Release 2

MDHT Example Project

Optional Subtitle



**PROTOTYPE: FOR DISCUSSION
AND DEMONSTRATION USE ONLY**

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Acknowledgments

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Revision History

Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	December 2010	Dave Carlson	Updated model content and publication format

Chapter 1

INTRODUCTION

Topics:

- *Overview*
- *Approach*
- *Scope*
- *Audience*
- *Organization of This Guide*
- *Use of Templates*
- *Conventions Used in This Guide*

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The data specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

Approach

Working with specifications generated from formal UML models provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

When valued in an instance, the template identifier (`templateId`) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a `templateId` to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. This implementation guide asserts when `templateIds` are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have `templateIds`).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the `templateId` and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

```
[<type of template>: templateId <XXXX.XX.XXX.XXX>]
```

Description of the template will be here

1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
2. **SHALL** contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) **STATIC** (CONF:<number>).
3.

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (**SHALL** , **SHOULD** , **MAY** , etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, " **MAY** contain 0..1" and " **SHOULD** contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

- 0..1 as zero to one present
- 1..1 as one and only one present
- 2..2 as two must be present
- 1..* as one or more present
- 0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL**, **SHOULD**, **MAY**, etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. The use of **SHALL** requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

1. **SHALL** contain [1..1] component/structuredBody (CONF:4082).
 - a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it
 - a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
 - b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
 - a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within this implementation guide are formatted WITHOUT typical **KEYWORD** and **XML** element styles. A WIKI site is available if you would like to make a comment to be considered for the next release of CCD: http://wiki.hl7.org/index.php?title=CCD_Suggested_Enhancements The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

1. The value for "Observation / @moodCode" in a problem observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**. (CONF: 814).
2. A problem observation **SHALL** include exactly one Observation / statusCode. (CONF: 815).
3. The value for "Observation / statusCode" in a problem observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**. (CONF: 816).
4. A problem observation **SHOULD** contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).

Figure 3: CCD conformance statements example

Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document are to be interpreted as described in the [HL7 Version 3 Publishing Facilitator's Guide](#):

- **SHALL**: an absolute requirement
- **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

XML Examples

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
...
</ClinicalDocument>
```

Figure 4: ClinicalDocument example

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

Chapter

2

DOCUMENT TEMPLATES

Topics:

- [General Header Constraints](#)

This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

General Header Constraints

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.3]

This section describes constraints that apply to the H and P Note and to other types of CDA documents defined for general exchange. The template defined here should be reused wherever these general header constraints are applied.

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named.

When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element.

Events occurring at a single point in time that are represented in the Clinical Document header will in general be precise to the day. These point-in-time events are the time of creation of the document; the starting time of a participation by an author, data enterer, authenticator, or legal authenticator; or the starting and ending time of an encounter.

Within the specification, all telephone numbers are to be encoded using a grammar which is a restriction on the TEL data type and RFC 2806. It simplifies interchange between applications as it removes optional URL components found in RFC 2806 that applications typically do not know how to process, such as ISDN sub-address, phone context, or other dialing parameters.

Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: <http://www.hl7.org/oid>.

Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at:

<http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration>.

The manner in which the OID root is obtained is not constrained by this DSTU.

1. **SHALL** conform to CDA Clinical Document
2. **SHALL** contain exactly one [1..1] code (CONF-CONSOL-45)
 - Specifies the type of the clinical document.
3. Contains exactly one [1..1] confidentialityCode
 - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
4. **SHALL** contain exactly one [1..1] effectiveTime (CONF-CONSOL-46)
 - Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.
5. **SHALL** contain exactly one [1..1] id (CONF-CONSOL-47)
 - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.
6. **SHALL** contain exactly one [1..1] languageCode (CONF-CONSOL-48)
7. **SHALL** contain exactly one [1..1] realmCode/@code = "US" (CONF-CONSOL-49)
8. **SHALL** contain exactly one [1..1] title (CONF-CONSOL-50)

- Specifies the local name used for the document. Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.
9. **SHALL** contain exactly one [1..1] `typeId` (CONF-CONSOL-51)
 - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
 10. Contains at least one [1..*] `author`
 11. Contains zero or one [0..1] `dataEnterer`
 12. Contains exactly one [1..1] `custodian`
 13. Contains zero or more [0..*] `informationRecipient`
 14. Contains zero or one [0..1] `legalAuthenticator`
 15. Contains zero or more [0..*] `authenticator`
 16. **SHALL** satisfy: All `patient`, `guardianPerson`, `assignedPerson`, `maintainingPerson`, `relatedPerson`, `intendedRecipient/informationRecipient`, `associatedPerson`, and `relatedSubject/subject` elements have a name. (CONF-CONSOL-1)
 17. **SHALL** satisfy: All `patientRole`, `assignedAuthor`, `assignedEntity[not(parent::dataEnterer)]` and `associatedEntity` elements have an `addr` and `telecom` element. (CONF-CONSOL-2)
 18. **SHOULD** satisfy: All `guardian`, `dataEnterer/assignedEntity`, `relatedEntity`, `intendedRecipient`, `relatedSubject` and `participantRole` elements have an `addr` and `telecom` element. (CONF-CONSOL-3)
 19. **SHALL** satisfy: All `guardianOrganization`, `providerOrganization`, `wholeOrganization`, `representedOrganization`, `representedCustodianOrganization`, `receivedOrganization`, `scopingOrganization` and `serviceProviderOrganization` elements have `name`, `addr` and `telecom` elements. (CONF-CONSOL-4)
 - When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the `nullFlavor` attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.
 20. **SHALL** satisfy: Times or time intervals found in the `ClinicalDocument/effectiveTime`, `author/time`, `dataEnterer/time`, `legalAuthenticator/time`, `authenticator/time` and `encompassingEncounter/effectiveTime` elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-CONSOL-5)
 21. **SHALL** satisfy: Times or time intervals found in the `asOrganizationPartOf/effectiveTime`, `asMaintainedEntity/effectiveTime`, `relatedEntity/effectiveTime`, `serviceEvent/effectiveTime`, `ClinicalDocument/participant/time`, `serviceEvent/performer/time` and `encounterParticipant/time` **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-CONSOL-6)
 22. **SHALL** satisfy: Telephone numbers match the regular expression pattern `tel:\+?[-0-9().]+` (CONF-CONSOL-7)
 - The `telecom` element is used to provide a contact telephone number for the various participants that require it. The value attribute of this element is a URL that specifies the telephone number, as indicated by the `TEL` data type.
 - All telephone numbers are to be encoded using a restricted form of the `tel:` URL scheme. A telephone number used for voice calls begins with the URL scheme `tel:`. If the number is a global phone number, it starts with a plus (+) sign. The remaining number is made up of the dialing digits and an optional extension and may also contain visual separators.
 23. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-CONSOL-8)
 24. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-CONSOL-9)
 - There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any `telecom` element that uses a flavor of null (has a `nullFlavor` attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.
 25. **SHALL** satisfy: The extension attribute of the `typeId` element is `POCD_HD000040`. (CONF-CONSOL-10)
 26. **SHALL** satisfy: The `id/@root` attribute is a syntactically correct UUID or OID. (CONF-CONSOL-11)

- 27. SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9]. (CONF-CONSOL-12)
- 28. SHALL** satisfy: OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID SHALL be in the form ([0-2])(.[1-9][0-9]*|0))+. (CONF-CONSOL-13)
- Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: <http://www.hl7.org/oid>.
- Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at: <http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration>.
- The manner in which the OID root is obtained is not constrained by this DSTU.
- 29. SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-CONSOL-14)
- OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
- 30. SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-CONSOL-15)
- 31. SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-CONSOL-16)
- 32. SHALL** satisfy: The CC portion languageCode, if present, SHALL be an ISO-3166 country code in uppercase. (CONF-CONSOL-17)
- 33. SHALL** satisfy: Both setId and versionNumber SHALL be present or both SHALL be absent. (CONF-CONSOL-18)
- The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.
- 34. SHALL** satisfy: The @extension and/or @root of setId and id SHALL be different when both are present. (CONF-CONSOL-19)
- 35. SHALL** satisfy: A copyTime element SHALL NOT be present. (CONF-CONSOL-20)
- The ClinicalDocument/copyTime element has been deprecated in CDA R2.
- 36. SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-CONSOL-21)
- 37. SHALL** satisfy: A patient/birthTime element SHALL be present. The patient/birthTime element SHALL be precise at least to the year, and SHOULD be precise at least to the day, and MAY omit time zone. If unknown, it SHALL be represented using a flavor of null. (CONF-CONSOL-22)
- 38. SHALL** satisfy: A patient/administrativeGenderCode element SHALL be present. If unknown, it SHALL be represented using a flavor of null. Values for administrativeGenderCode SHOULD be drawn from the HL7 AdministrativeGender vocabulary. (CONF-CONSOL-23)
- TODO: add OCL test for terminology
- 39. MAY** satisfy: The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode MAY be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they SHOULD be encoded using the appropriate HL7 vocabularies. (CONF-CONSOL-24)
- 40. SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-CONSOL-25)
- 41. MAY** satisfy: The providerOrganization element is present. (CONF-CONSOL-26)
- 42. SHALL** satisfy: The author/time element is present. (CONF-CONSOL-27)
- The author/time element represents the start time of the author's participation in the creation of the clinical document.
- 43. SHALL** satisfy: The assignedAuthor/id element is present. (CONF-CONSOL-28)
- 44. SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-CONSOL-29)

- 45. SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-CONSOL-30)
- 46. MAY** satisfy: The dataEnterer/time element MAY be present. If present, it represents the starting time of entry of the data. (CONF-CONSOL-31)
- 47. MAY** satisfy: The informant element is present. (CONF-CONSOL-32)
- 48. SHALL** satisfy: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element SHALL be present. (CONF-CONSOL-33)
- 49. SHALL** satisfy: When the informant is a healthcare provider with an assigned role, the informant SHALL be represented using the assignedEntity element (CONF-CONSOL-34)
- Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
 - TODO: how to determin if informant is a healthcare provider? condition for implementing OCL
- 50. SHALL** satisfy: Allowable values for informant/relatedEntity/@classCode SHALL be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-CONSOL-35)
- When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient.
- The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.
- 51. SHALL** satisfy: When relatedEntity/@classCode is PRS, values in relatedEntity/code SHALL come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-CONSOL-36)
- 52. SHALL** satisfy: When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode SHALL be set to CON to indicate that this person is a contact. (CONF-CONSOL-37)
- Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.
- 53. SHALL** satisfy: When the informant is a healthcare provider without an assigned role, the informant SHALL be represented using the relatedEntity element and the value of relatedEntity/@classCode SHALL be set to PROV. (CONF-CONSOL-38)
- A health care provider who does not have an assigned role at the institution may provide information. To record an informant that does not have an assigned role that can be represented within the context of the document, the information will be represented using the relatedEntity element and the value of relatedEntity/@classCode will be set to PROV.
- 54. SHOULD** satisfy: When the informant is a healthcare provider, the value of relatedEntity/code SHOULD be present and indicate the type of healthcare provider. (CONF-CONSOL-39)
- 55. MAY** satisfy: The ClinicalDocument/informationRecipient element MAY be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization SHALL be present. (CONF-CONSOL-40)
- 56. SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in legalAuthenticator. (CONF-CONSOL-41)
- 57. SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in an authenticator element. (CONF-CONSOL-42)
- 58. SHOULD** satisfy: Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements SHALL be precise to the day, SHALL include a time zone if more precise than to the day, and SHOULD be precise to the second. (CONF-CONSOL-43)
- Should portion of CON-HP-10 constrain
- 59. SHOULD** satisfy: Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time SHALL be precise at least to the year, SHOULD be precise to the day, and MAY omit time zone. (CONF-CONSOL-44)
- Should portion of CON-HP-11 constrain

General Header Constraints example

Chapter

3

SECTION TEMPLATES

Chapter

4

CLINICAL STATEMENT TEMPLATES

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

Chapter

5

OTHER CLASSES

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.

Chapter 6

VALUE SETS

The following tables summarize the value sets used in this Implementation Guide.

REFERENCES

- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD) A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record® (CCR) April 01, 2007 available through [HL7](#) .
- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: [Quality Reporting Document Architecture \(QRDA\)](#)
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- [LOINC®](#) : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
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