Australian Government

Australian Digital Health Agency

Specialist Letter
My Health Record Conformance Profile

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1 Introduction

1.1 Purpose

This document summarises the requirements for producing and consuming systems of the Specialist Letter clinical document ("Specialist Letter") when connecting to the national My Health Record (MHR) system.

These conformance requirements are in addition to the *Clinical Documents –Common Conformance Profile* [AGENCY2014]. Together, these two conformance profile documents represent the complete conformance requirements for the Specialist Letter.

1.2 Intended audience

The intended audience includes:

• healthcare providers

• vendors and developers of connecting systems, and

• software test laboratories.

1.3 Scope

The scope of this conformance profile is the use of a Specialist Letter in the context of the national MHR system. The conformance requirements do not apply when a Specialist Letter is sent point-to-point.

2 Conformance requirements

2.1 Introduction

This section describes the conformance requirements specific to the Specialist Letter clinical document type.

2.2 Relevant specifications

The detailed conformance requirements are listed in Table 1.

Table 1 - Specifications for Specialist Letter

Specification	Notes
Specialist Letter Structured Content Specification [AGENCY2011]	Specifies the data elements and constrained values for a clinical document at a logical level.
Specialist Letter CDA Implementation Guide [AGENCY2012a]	Specifies the mapping from the structured content specification into a clinical document using an HL7 CDA structure.

2.3 Conformance requirements for producing systems

2.3.1 Objects of conformance

The objects of conformance are subject to the following requirements:

1   Specialist Letters MAY be produced by:

   a   clinical information systems, and

   b   contracted service provider (CSP) systems.

2   Specialist Letters SHALL NOT be produced by:

   a   registered repositories

   b   registered consumer portals, or

   c   registered provider portals.

2.3.2 Conformance levels

A Specialist Letter sent to the My Health Record System SHALL conform to the requirements for one, and only one, of the following conformance levels: 1A, 1B, 2, 3A, or 3B, as defined in the common conformance profile [AGENCY2014].

2.3.3 Temporary relaxation of inclusion of HPI-I

The *Specialist Letter Structured Content Specification* [AGENCY2011] and the *Specialist Letter CDA Implementation Guide* [AGENCY2012a] include mandatory conformance requirements for the inclusion of HPI-Is. These specifications state the conformance requirement:

"The value of one Entity Identifier SHALL be an Australian HPI-I"

This applies to the following data elements:

- Document Author > Participant > Entity Identifier

- Referrer > Participant > Entity Identifier

- Usual GP > Participant > Entity Identifier

- Diagnostic Investigations > Requested Service > Service Provider > Participant > Entity Identifier, and

- Recommendations > Recommendation > Addressee (Person) > Participant > Entity Identifier.

The mandatory requirements for an HPI-I for these data elements are temporarily modified.

1   The value of one Document Author > Participant > Entity Identifier SHALL be an HPI-I if one is present in the Specialist Letter producing system, otherwise it SHALL have a value that identifies the document author, and the value SHALL NOT be a nullFlavor.

2   If Usual GP is present in a Specialist Letter, the value of one Usual GP > Participant > Entity Identifier, SHALL be an HPI-I if one is present in the Specialist Letter producing system, otherwise it SHALL have a value that identifies the usual GP and the value SHALL NOT be a nullFlavor.

3   If Diagnostic Investigations > Requested Service > Service Provider is present in a Specialist Letter, the value of one Diagnostic Investigations > Requested Service > Service Provider > Participant > Entity Identifier SHALL be an HPI-I if one is present in the Specialist Letter producing system, otherwise it SHALL have a value that identifies the diagnostic investigations service provider (person), and the value SHALL NOT be a nullFlavor.

Notes:

a   The common conformance profile [AGENCY2014] provides requirements for the inclusion of a local identifier.

b   The relaxation is only available to specific healthcare provider organisations, at the discretion of the MHR System Operator. The relaxation is provided to allow time for large healthcare provider organisations to incorporate HPI-Is for their personnel in their systems.

2.3.4   Unknown entity identifiers for referrer and addressee

The *Specialist Letter Structured Content Specification* [AGENCY2011] and the *Specialist Letter CDA Implementation Guide* [AGENCY2012a] include a mandatory conformance requirement for the inclusion of an HPI-I for the entity identifier of the referrer, and a mandatory conformance requirement for the inclusion of an HPI-O for the entity identifier of the referrer's employer. These identifiers may be obtained from an eReferral conforming to the *eReferral CDA Implementation Guide* [AGENCY2012b], but cannot necessarily be obtained if the referral was in some other format, or if the eReferral was created by a software system using the temporary relaxation of the requirement to include the referrer's HPI-I.

The same issue is present with the recommendation addressee, which may be a person or an organisation.

These requirements for mandatory inclusion of the HPI-I and HPI-O for a referrer are modified here to allow a Specialist Letter to be created regardless of the format or existence of the referral. Similar modifications are made for addressee (person) and addressee (organisation).

1   The value of one Referrer > Participant > Entity Identifier SHALL be an HPI-I if one is present in the Specialist Letter producing system, otherwise the value SHALL either have a value that identifies the referrer or the value SHALL be the nullFlavor "UNK".

Notes:

a   This means that:

i   If the software received an eReferral containing the referrer's HPI-I then it must be included in the Specialist Letter created in response to the eReferral.

ii   If the eReferral contains a local identifier then it may be included in the Specialist Letter.

   iii If the referrer's HPI-I is not present in a referral then the software may (but need not) obtain the referrer's HPI-I by searching for one in the Healthcare Identifier service.

  b The nullFlavor "UNK" means "unknown"; that is, a proper value is applicable, but not known.

  c An entity identifier created using a nullFlavor "UNK" is shown below:

```
<ext:asEntityIdentifier classCode="IDENT">
    <ext:id nullFlavor="UNK" />
                </ext:asEntityIdentifier>
```

2 The value of one Referrer > Participant > Person or Organisation or Device > Person > Employment Detail > Employer Organisation > Entity Identifier SHALL be an HPI-O if one is present in the Specialist Letter producing system, otherwise the value SHALL either have a value that identifies the referrer's employer, or the value SHALL be the nullFlavor "UNK".

  Note: A number of options are available for creating a local entity identifier for an organisation, such as using the Australian Business Number.

3 If a recommendation addressee (person) is recorded in a Specialist Letter, the value of one Recommendations > Recommendation > Addressee (Person) > Participant > Entity Identifier SHALL be an HPI-I if one is present in the Specialist Letter producing system, otherwise the value SHALL either have a value that identifies the addressee (person), or the value SHALL be the nullFlavor "UNK".

4 If the addressee is a participant identified in an eReferral conforming to the *eReferral CDA Implementation Guide* [AGENCY2012b], (e.g. the address may be the usual GP) then the addressee's identifiers SHALL be copied from the eReferral.

5 If the addressee's employment detail is recorded in a Specialist Letter, the value of one Recommendations > Recommendation > Addressee (Person) > Participant > Person or Organisation or Device > Person > Employment Detail > Employer Organisation > Entity Identifier SHALL be an HPI-O if one is present in the Specialist Letter producing system, otherwise the value SHALL either have a value that identifies the addressee's employer or the value SHALL be the nullFlavor "UNK".

6 If a recommendation addressee (organisation) is recorded in a Specialist Letter, the value of one Recommendations > Recommendation > Addressee (Organisation) > Participant > Entity Identifier SHALL be an HPI-O if one is present in the Specialist Letter producing system, otherwise the value SHALL either have a value that identifies the addressee (organisation) or the value SHALL be the nullFlavor "UNK".

2.3.5 No referrer

The *Specialist Letter Structured Content Specification* [AGENCY2011] and the *Specialist Letter CDA Implementation Guide* [AGENCY2012a] include a mandatory inclusion of details about the referrer. However it is possible that there was no referral from a healthcare provider (i.e. there has been a self-referral by the subject of care).

The requirement for mandatory inclusion of referrer details is modified here to enable a Specialist Letter to be produced when there is no referrer.

1 The Specialist Letter Referrer data element MAY be omitted if the Specialist Letter producing system does not contain any information about a referrer but SHALL NOT be omitted if information about the referrer is known and can be used to create the Referrer data element.

  Notes:

  a The effect is that the cardinality of Referrer is changed from 1..1 to 0..1.

  b This means that if the software contains information about the referrer, then the referrer details shall be included in the Specialist Letter. Information about the referrer is present in the software if:

    i   the software received an eReferral conforming to the *eReferral CDA Implementation Guide* [AGENCY2012b], and

    ii   the software received a eReferral in some other electronic format, or

    iii   information from a paper-based referral was entered into the software.

2.3.6   Address of the individual

When authoring the individual's address, the document SHALL contain one of the followings:

- an address, or

- a nullflavor, or

- both, BUT NOT

- an address AND an MSK nullflavor.

Rationale:

The address of the healthcare individual can be masked due to privacy or safety concerns.

Additional Notes:

The document author is permitted to suppress or not include the individual's residential address through the use of nullflavor. If the address is known, but not included in the document, then it is preferred the "MSK" nullflavor is used. The masking of the address may be used when there are patient privacy or safety concerns.

It is prohibited to include a MSK nullflavor AND an address because a masked address should not be available in the CDA/XML document.

Other nullflavors are also permitted.

2.3.7   Document subtype

To support clinical document discoverability, the producing system is encouraged to include a document subtype in the clinical document. The document subtype is intended to assist healthcare providers and individuals to discover the most relevant clinical documents and identify the clinically relevant content easily in the healthcare individual's MHR.

The Document Type Register is a comprehensive list of all document types and its associated subtypes supported by the MHR system. Each document type and subtype will be supplemented with a description to inform implementers about the intention of the subtypes. Implementers should refer to the Agency's Developer Centre (https://developer.digitalhealth.gov.au) for information on how to access the Document Type Register.

The national Document Type Register will be maintained by the Agency and it may change over time for additional or to update subtypes. Because the locally stored list of subtypes provided by the CIS is sourced from the national Document Type Register and cached periodically it is expected the local list of subtypes won't perfectly align to the national Document Type Register. This is acceptable provided that the update of the local Document Type Register will be performed by the CIS within a reasonable timeframe. See requirement 2.3.7.5 for detail.

The conformance requirements in this section refer to the local version of Document Type Register that is implemented within the local CIS at the time of authoring. See requirements 2.3.7.1 to 2.3.7.5 for the inclusion of subtypes known to the local CIS.

2.3.7.1 Document subtype name

If instantiating the document subtype, the producing system SHALL instantiate the following XPaths with the same subtype name:

- ClinicalDocument/code/originalText

- ClinicalDocument/title

This SHALL be one of the subtypes in the local Document Type Register for the document type.

Rationale:

To differentiate the document with a subtype and reflect the document subtype name in the MHR document title.

Additional Notes:

The local Document Type Register contains the list of document types and its subtypes for the My Health Record. Implementers should refer to the Agency's Developer Centre for information about how to access and sync with the national Document Type Register.

2.3.7.2 Authoring a document with subtype

When authoring the first version of a subtyped document, the document SHALL only contain a subtype that is "active" in the local system.

Rationale:

To ensure CIS's local document type register is updated regularly and transition to the new subtypes where appropriate. To prevent document rejection by the MHR system when the subtype becomes retired.

Additional Notes:

The first version of the document is a newly authored document that is authored at the first instance (i.e. new document set ID), and not a superseding document.

The local Document Type Register stored in the CIS may not be up to date with the version in the MHR system. Once the CIS has updated to a newer version of the national Document Type Register, the CIS must incorporate any new "active" subtypes for authoring.

2.3.7.3 Superseding a document with the same subtype

When superseding a subtyped document, the subtype of the superseding document SHOULD be the same as the subtype of the preceding document and that subtype MAY be deprecated or retired.

Rationale:

To ensure document versions in the My Health Record System contain consistent subtypes.

Additional Notes:

The system that is superseding a document with the same subtype should acquire the subtype from the superseded document, and not from a source (i.e. Document Type Register) that might encourage an inconsistent subtype.

2.3.7.4 Superseding a document with a different subtype

When superseding a document with a subtype that is different from that of the preceding document, the subtype of the superseding document:

- SHALL NOT be "retired" in the local system, and

- SHALL NOT contradict the content of the clinical document.

Rationale:

To allow flexibility for CIS to update and correct the document subtype from the preceding document where appropriate.

Additional Notes:

A superseding document may contain a different subtype from the preceding document. For example, to correct an incorrect subtype; to transition to a more specific subtype; or up to date subtype.

The subtype of the subsequent versions of the document must be relevant.

2.3.7.5 Document Type Register

The producing system SHALL provide a mechanism to update the local Document Type Register in real time, on a schedule or on request (e.g. manual input).

Rationale:

To ensure the producing system maintains an up to date Document Type Register in the local CIS. Prevent document rejection by the MHR system when subtype becomes retired.

2.3.7.6 Automated assignment of subtype

When authoring a subtyped document, the producing system SHOULD support automated assignment of the subtype to the document.

Rationale*:*

To promote software usability and conformity when CIS automatically subtypes a document. To mitigate the risk of human errors when document author manually selects a subtype.

2.4   Conformance requirements for consuming systems

2.4.1   Objects of conformance

The objects of conformance requirements include:

Specialist Letters MAY be consumed by:

     a   clinical information systems

     b   CSP systems

     c   registered consumer portals

     d   registered provider portals, and

     e   registered repositories.

2.4.2   Search or filter subtype

When viewing a subtyped document, the CIS SHOULD provide a mechanism to search or filter a particular subtype(s).

Rationale:

Allow robust searching or filtering functionality in the CIS to discover the relevant document subtypes easily.

Additional Notes:

Depending on the software design, the viewing functions may present a long list of subtypes for the healthcare providers to choose from. The CIS should make it easy for healthcare providers to discover the subtyped documents.

Acronyms

Acronym	Description
CDA	Clinical Document Architecture
CIS	clinical information system
CSP	contracted service provider
MSK	masked
UNK	unknown

Glossary

Term	Description
clinical document	A digital file containing personal health information about an individual, containing unstructured (narrative) information and optionally structured (atomic) information.
Clinical Document Architecture (CDA)	An XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents exchanged between health software systems.
clinical information system	A system that deals with the collection, storage, retrieval, communication, and use of health-related data, information and knowledge pertaining to subjects of care [AS5021]. The system may comprise one or more applications or components.
conformance	Conformance is a measurement (by testing) of the adherence of an implementation to a specification or standard.
consumer	In this document, 'consumer' refers to a software system that has the role of being a consumer of Specialist Letters.
contracted service provider	An entity that may offer health software as a service, and support access to the MHR system on behalf of healthcare organisations. A CSP provides under a contract with the healthcare provider organisation: a) information technology services relating to the MHR system; or b) health information management services relating the MHR system. (Section 5 Personally Controlled Electronic Health Records Act 2012.)
contracted service provider system	A software system operated by a CSP that deals information and knowledge pertaining to subjects of care [AS5021]. The system may comprise one or more applications or components. A CSP system may perform some or all of the functions of a clinical information system.
healthcare consumer	A person who is the subject of care. (For the software system, see 'consumer'.)
individual	A person who is, or could be, seeking care in Australia. Individual is sometimes referred to as patient, client and consumer. For the purposes of the My Health Record system, an individual must have an IHI.
MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
producing system	A software system that has the role of generating and issuing conformant clinical documents suitable for use by other digital health participants.
registered consumer portal	A third-party portal used by healthcare recipients to access information on the MHR system.
registered provider portal	A third-party portal used by healthcare providers to access information on the MHR system.
registered repository	A third-party repository used to store clinical documents and other clinical data that connects to the MHR system. A repository may store clinical documents in either a proprietary format or a CDA format.
SHALL	When appearing in a conformance requirement, the verb SHALL indicates a mandatory requirement. Its negative form SHALL NOT indicates a prohibition.
Specialist Letter	The Specialist Letter is the clinical document used in replying to a referral or reporting on a health event.

References

[AGENCY2011]   *Specialist Letter Structured Content Specification, Version 1.1*, Australian Digital Health Agency, 2 December 2011, https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-1753-2014/nehta-0983-2011

[AGENCY2012a]   *Specialist Letter CDA Implementation Guide, Version 1.3*, Australian Digital Health Agency, 7 Mar 2012, https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-1753-2014/nehta-0966-2012

[AGENCY2012b]   *eReferral CDA Implementation Guide, Version 2.2*, Australian Digital Health Agency, 7 Mar 2012, https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-0936-2012/nehta-0967-2012

[AGENCY2014]   *Clinical Documents – Common Conformance Profile, Version 1.5*, Australian Digital Health Agency, 2014, https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-1962-2014/nehta-1812-2014

[AS5021]   *AS 5021:2005 - The language of health concept representation*, Standards Australia, 2005