

## Pharmacist Shared Medicines List My Health Record Conformance Profile

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# **Document information**

# Key information

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## Product or document version history

Product or document version	Date	Release comments
v1.0		First Release
v1.1		Product name changed from "Pharmacist Curated Medicines List" to "Pharmacist Shared Medicines List"
v1.1.1		Introduced HPI-I exemptions. Incorporated feedback from peer review.
V1.1.1	13/05/2025	The document presentation has been enhanced to align with current branding guidelines; however, the content has not been changed.

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# 1 Introduction

### 1.1 Purpose

This document summarises the requirements for software systems that produce Pharmacist Shared Medicine List (PSML) clinical documents.

Clinical document producing systems author clinical documents for distribution to clinical document consuming systems.

Clinical document consuming systems obtain clinical documents created by clinical document producing systems and provide the content to healthcare providers.

This document does not list the requirements for the distribution of clinical documents between producing systems and consuming systems. There are several mechanisms to achieve this, such as direct exchanges between healthcare providers, and indirect exchanges, mediated by local and national shared repositories, such as the My Health Record system.

Where this document conflicts with the Core Level One Clinical Document CDA Implementation Guide, the requirements within this profile override the Implementation Guide.

### 1.2 Intended audience

The intended audience includes the following organisations:

- healthcare providers
- developers and vendors of digital health systems
- software test laboratories.

### 1.3 Scope

The scope of this conformance profile is the production of PSML clinical documents. This includes, but is not limited to:

 documents created specifically to be sent to the My Health Record system by clinical information systems, contracted service provider (CSP) systems, or consumer portals.

### 1.4 Overview

Medicines are the most common treatment used in health care, and 50% of older Australians (aged 65 years and older) can be taking five or more medicines daily, with around 10% using 10 or more medicines daily. Management of multiple medicines could be challenging, especially for older Australians. It is common for a consumer to access multiple health services which can result in care being provided simultaneously, at different times, or transferred back and forth between providers. When a consumer's care is transferred there is an increased risk of information being lost, miscommunicated or misinterpreted. More than 50% of medication errors occur at transitions of care, and a third of these errors have the potential to cause harm or contribute to suboptimal care.

The 'pharmacist shared medicines lists' (PSML) is designed for consumers with chronic diseases(s) and/or multiple medications to improve information sharing between health professionals; ensure continuity of medicine management for consumers that transfer between care settings; and to provide timely access to pharmacists shared medicines lists.

This document will make medicines information available in My Health Record, and to support its meaningful clinical use, by providing pathways for the upload of pharmacists shared medicines lists to the My Health Record system.

## 2 Pharmacist Shared Medicines List

Generated Date : 22 Jan 2020, 3:07 pm Generated By : Lloyd Armstrong Element : Pharmacist Shared Medicines List Element guid : {8B3CD2E5-606E-4f66-AFEC-F67BD49297DB}

### 2.1 Relevant specifications

Related specifications are listed below:

- 1 Common Conformance Profile for Clinical Documents [AGENCY2018a] provides common Conformance Requirements which must be adhered to unless specifically contradicted in this document.
- 2 Core Level One Clinical Document Structured Content Specification [AGENCY2018b] - specifies the data elements permissible in the clinical document at a logical level
- 3 Core Level One Clinical Document CDA Implementation Guide [AGENCY2018c] specifies the mapping from the structured content specification into a clinical document using an HL7 CDA structure.

The Core Level One Clinical Document specifications are generic, not specific to PSML and not fit for purpose without additional implementation guidance. See section 2.3 for implementation guidance specific to PSML.

028153	Allowed types of producers PSML clinical documents MAY be produced by:	
	contracted service provider (CSP) systems.	
Priority	Optional	
Additional notes	It should not be assumed that systems not of the above types will be allowed to author and upload PSML's into My Health Record.	
024569	Disallowed types of producers	
	A PSML SHALL NOT be produced by a:	
	registered consumer portal	
	registered repository	
	registered portal operator (mobile gateway), or	
	registered provider portal.	
Priority	Mandatory	
Additional notes	The risk profile for these types of producers has not been assessed. It is not appropriate for these producers to upload PSML documents until that risk profile is understood.	

## 2.2 Objects of conformance

## 2.3 Conformance criteria for producing systems

In some workflows the system that produces the PSML PDF may not always be the authoring system, especially if a PSML PDF is created by an external system and attached to the CDA document. In these scenarios the content of the PSML PDF uploaded by the authoring system is unable to be changed.

The objects of conformance are subject to the following requirements:

027987	Levels of conformance
	A PSML sent to the My Health Record system <b>SHALL</b> conform to the requirements for conformance level 1A as defined in the Common <i>Conformance Profile for Clinical Documents</i> [AGENCY2018a].
Priority	Mandatory
028034	Content of PSML
020004	The producing system <b>SHALL</b> have the capability to include in the document all medicines the patient record states an individual is known to be taking.
Priority	Mandatory
Additional notes	This includes prescription medicines, non-prescription medicines and complementary medicines and applies to all types of producing systems including those used for the management of Dose Administration Aids.
029202	Medicine item
	If the producing system authors the PSML PDF, then the producing system
	SHALL include the medicine item in the attached PSML PDF as either:
	brand name
	active ingredient, or
	• both.
Priority	Conditional
Additional notes	It is important for the PSML to provide enough information to uniquely identify each medicine listed.
029208	Medicine direction
	If the producing system authors the PSML PDF, then the producing system <b>SHALL</b> include the direction of each medicine item within the attached PSML PDF.
Priority	Conditional
Additional notes	The medicine direction should include dose of administration and frequency.

029209	Medicine item list
	If the producing system authors the PSML PDF, then the producing system <b>SHOULD</b> list medicine items in a table and column format within the attached PSML PDF.
Priority	Recommended
Additional notes	It is important for the PSML to provide medicine information in a user consistent format.
029203	Producing healthcare organisation
029203	If the producing system authors the PSML PDF, then the producing system <b>SHOULD</b> include the authoring healthcare organisation's name ir the attached PSML PDF.
Priority	Conditional
Additional notes	It is important to be able to easily identify the organisation that authored the PSML.
029204	Producing healthcare organisation contact details
	If the producing system authors the PSML PDF, then the producing system <b>SHOULD</b> include the authoring healthcare organisation's contact details within the attached PSML PDF.
Priority	Recommended
Additional notes	It is beneficial to provide contact details for the authoring healthcare organisation.
029205	Author role
	If the producing system authors the PSML PDF and the author is not a pharmacist, then the producing system <b>SHOULD</b> include the authoring providers role in the attached PSML PDF.
Priority	Recommended
Additional notes	If the PSML author is not a pharmacist, it is important to provide context and capture the authoring healthcare providers role.
029454	Dece Administration Aide
028154	Dose Administration Aids
	Software for Dose Administration Aids <b>SHALL</b> have the capability to include in the document all packed and non-packed medicines the patient record states an individual is known to be taking.
Priority	Mandatory
Additional notes	It is important for the PSML to be as complete as possible.

029206	Patient photo
	If the producing system generates the PSML PDF, it <b>SHALL NOT</b> contain a patient photo.
Priority	Conditional
Additional notes	In those scenarios the authoring system may accept an externally scanned PDF and not have control over the contents of the PSML PDF.
029207	No communication detail for the consumer
	If the producing system authors the PSML PDF, then the producing system <b>SHALL NOT</b> include communication contact detail for the consumer within the PDF when uploading to My Health record.
Priority	Conditional
Additional notes	The communication contact details of the consumer will be omitted due to privacy or safety concerns.
028678	Prompt to upload recent PSML
	If the producing system creates a PSML that is clinically different from a previously uploaded PSML from the same producing system then the system <b>SHOULD</b> prompt the user to upload the most recent PSML to the My Health Record.
Priority	Recommended
Additional notes	Changes to an individual's personal details, contact details, demographic data or other administrative details are not considered to be clinically relevant.

### 2.3.1 Application of Core Level One Clinical Document specifications

The Core Level One Clinical Document is an open specification that requires constraints to make a PSML fit for purpose. The requirements in this section constrain the Core Level One Clinical Document CDA Implementation Guide and should be considered during the software design stage.

027988	Subject of care identifier
	When instantiating the subject of care, the document <b>SHALL</b> contain one
	and only one personal identifier and that identifier <b>SHALL</b> be an Individual Healthcare Identifier (IHI).
	Mondatan
Priority	Mandatory
027991	Subject of care address
021331	-
	When instantiating the subject of care, the document <b>SHALL</b> contain:
	an address (of any type), OR
	a nullflavor (of any type)
	• or both, BUT NOT
	<ul> <li>an address (of any type) AND an MSK nullflavor.</li> </ul>
Priority	Mandatory
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 <b>AND</b> an address because a masked address should not be available in the CDA/XML document. Other nullflavors are also permitted.
027989	Document author
	When instantiating the document author, the document <b>SHALL</b> instantiate the document author as a person.
Priority	Mandatory
Additional notes	The document author must be instantiated as a person and must not be an organisation or device.

027992	Document author organisation name
	When instantiating the document author, the document <b>SHALL</b> contain one and only one organisation name represented as:
	<ul> <li>Document Author &gt; Participant &gt; Person or Organisation or Device &gt; Person &gt; Employment Detail &gt; Employer Organisation &gt; Organisation &gt; Organisation Name</li> </ul>
	Represented via the following XPATH:
	<ul> <li>/ClinicalDocument/author/assignedAuthor/assignedPerson/ext:asEm ployment/ext:employerOrganization/asOrganizationPartOf/wholeOrga nization/name</li> </ul>
Priority	Mandatory
Additional notes	Implementers should note that this requirement effectively makes the "Employment Detail" section mandatory.
027993	Document author workplace address
	When instantiating the document author, the document <b>SHALL</b> contain one and only one value for healthcare provider individual's workplace address and that address is an Australian address.
Priority	Mandatory
Additional notes	The document <b>MAY</b> contain other non-workplace addresses. See requirement 024982.
028630	Document Author Entity Identifier value
	When instantiating the document author, the document <b>SHALL</b> contain one and only one personal identifier that is a Healthcare Provider Identifier for Individual (HPI-I), otherwise it <b>SHALL</b> have a value that identifies the document author, and that value <b>SHALL NOT</b> be a nullflavor.
Priority	Mandatory
Additional notes	The relaxation of the mandatory requirement to include an HPI-I is only available to specific healthcare provider organisations, at the discretion of the My Health Record System Operator.
027995	Document author organisation identifier
	When instantiating the document author, the document <b>SHALL</b> contain one and only one organisation identifier and that identifier is a Healthcare Provider Identifier for Organisation (HPI-O).
Priority	Mandatory
	,

028068	Inclusion of PDF attachment
	The document <b>SHALL</b> contain one and only one PSML document that
	reflects the original PSML document.
_	The PSML document <b>SHALL</b> be a PDF packaged attachment.
Priority	Mandatory
Additional notes	Until the PSML can be represented with structured data it should only be made available in the My Health Record system in PDF format to ensure that the presentation and rendering of the data is as expected by the authoring healthcare provider.
	The PDF file is expected to be viewable by the healthcare individual and any healthcare provider that is a My Health Record participant. For example, the PSML document PDF files should not have any of these features:
	encryption
	password protection
	printing or copying restriction
	• embedded fonts (as not all PDF viewers support them).
028069	Referencing PSML PDF attachment
	The document <b>SHALL</b> contain the PDF (see requirement 028068) in ENCAPSULATED DATA with
	"templateID/@root="1.2.36.1.2001.1001.101.102.16883"
	under section with
	"templateID/@root="1.2.36.1.2001.1001.101.101.16886".
Priority	Mandatory
Additional notes	The document may contain other attachments (e.g. logos) that do not contain a PSML or any other medicines information.
	The requirement applies only to attachments that include PSML medicines.
027998	PDF attachment MIME type
	When instantiating a PDF attachment, the MIME type of the attachment <b>SHALL</b> be of .pdf application/pdf MIME type.
Priority	Mandatory
Additional notes	This requirement overrides Requirement 023741 in the Clinical Documents Common Conformance Profile.

027999	Document type		
	When instantiating the document type, the software SHALL use:		
	<ul> <li>the code "56445-0" in the code attribute of the code element of the clinical document;</li> <li>the OID in the codeSystem attribute of the code element of the clinical document SHALL be "2.16.840.1.113883.6.1"; and</li> </ul>		
	<ul> <li>the title element value of the clinical document SHALL be "Pharmacist Shared Medicines List".</li> </ul>		
Priority	Mandatory		
028000	Clinical document template identifier		
	When instantiating the templateid the software <b>SHALL</b> ensure that one instance of the clinical document:		
	<ul> <li>the root attribute of the templateId element SHALL be "1.2.36.1.2001.1001.100.1002.237"; and</li> </ul>		
	• the extension attribute of the templateId element SHALL be "1.0".		
Priority	Mandatory		
Additional notes	This is in addition to the template ID specified in the Core Level One Clinical Document CDA Implementation Guide.		

#### 2.3.1.1 Document author contact details

Clinical documents can support telecommunication and address details for participating healthcare providers. These commonly support entry of address, mobile phone, home phone, pager, fax and email address details as part of the system's healthcare provider record. Inclusion of personal provider contact details is typically supported on an optional basis. However, some clinical information systems automatically populate the relevant fields with personal provider details already stored in the system.

While inclusion of personal provider details may in some cases be useful for documents exchanged point-to-point between providers, this is of concern as this information becomes visible to consumers once they are uploaded to their My Health Record.

Note: Providers who have elected not to have their software automatically include any individual electronic contact details or address may still include these details where required in the narrative part of the document.

024980	Confirm author's personal electronic communication details to be included
	If the producing system captures the personal electronic communication details (e.g. email address, phone number or fax number) of the document author, the individual electronic communication details <b>SHALL NOT</b> be automatically included unless stated otherwise.
Priority	Conditional
Additional notes	Software that does not provide this option can conform to this requirement by not automatically inserting individual's personal electronic communication details into the document as appropriate.
	The software can also demonstrate conformance by not capturing the individual's personal electronic communication details in the CIS.
024982	Confirm author's personal address to be included
	If the producing system captures the personal address of the document author, the individual personal address <b>SHALL NOT</b> be automatically included unless stated otherwise.
Priority	Conditional
Additional notes	Software that does not provide this option can conform to this requirement by not automatically inserting individual's personal address details into the document as appropriate.
	The software can also demonstrate conformance by not capturing the individual's personal address details in the CIS.

#### 2.3.1.2 Primary Healthcare Provider

The primary healthcare provider can be instantiated as a person or an organisation, represented as a "PARTICIPANT" in the Core Level One Clinical Document CDA Implementation Guide and Structured Content Specification.

When the primary healthcare provider is instantiated as an organisation, the primary healthcare provider individual details are not permitted.

When the primary healthcare provider individual details are known, the "PARTICIPANT" should be instantiated as a person.

027990	Primary healthcare provider
	The document <b>SHALL</b> contain at most one primary healthcare provider. The primary healthcare provider <b>SHALL</b> have PARTICIPANT (/ClinicalDocument/participant) instantiated with a typeCode of "PART" and a functionCode of "PCP":
	<ul> <li>/ClinicalDocument/participant/@typeCode="PART"</li> </ul>
	<ul> <li>/ClinicalDocument/participant/functionCode/@code="PCP".</li> </ul>
Priority	Mandatory
028031	Primary healthcare provider organisation name
	If instantiating the primary healthcare provider as a person, the document <b>SHALL</b> contain one and only one organisation name represented as the following data element:
	<ul> <li>PARTICIPANT &gt; PARTICIPANT &gt; PERSON OR ORGANISATION OR DEVICE &gt; PERSON &gt; EMPLOYMENT DETAIL &gt; EMPLOYER ORGANISATION &gt; ORGANISATION &gt; Organisation Name</li> </ul>
	Represented in CDA using XPath notation as:
	<ul> <li>/ClinicalDocument/participant/associatedEntity/associatedPerson/ext :asE</li> </ul>
	mployment/ext:employerOrganization/asOrganizationPartOf/wholeOr gani zation/name
Priority	Conditional
Additional notes	Implementers should note that this requirement effectively makes the "Employment Detail" section mandatory.

028032	Primary healthcare provider organisation identifier
	If instantiating the primary healthcare provider, the document <b>SHOULD</b> contain a Healthcare Provider Identifier for Organisation (HPI-O) as an organisation identifier.
	Represented as the following data element if the primary healthcare provider is instantiated as a person:
	PARTICIPANT > PARTICIPANT > PERSON OR ORGANISATION OR DEVICE > PERSON > EMPLOYMENT DETAIL > EMPLOYER ORGANISATION > ORGANISATION > Entity Identifier
	Represented as the following data element if the primary healthcare provider is instantiated as an organisation:
	<ul> <li>PARTICIPANT &gt; PARTICIPANT &gt; Entity Identifier</li> </ul>
	Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as a person, as:
	<ul> <li>/ClinicalDocument/participant/associatedEntity/associatedPerson/ext :asE mployment/ext:employerOrganization/asOrganizationPartOf/wholeOr</li> </ul>
	gani zation/ext:asEntityIdentifier
	Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as an organisation, as:
	<ul> <li>/ClinicalDocument/participant/associatedEntity/scopingOrganization/ asOr ganizationPartOf/wholeOrganization/ext:asEntityIdentifier</li> </ul>
Priority	Recommended
028033	Primary Healthcare provider individual identifier
	If instantiating the primary healthcare provider as a person, the document <b>SHOULD</b> contain a Healthcare Provider Identifier for Individual (HPI-I) as a person identifier represented as the following data element:
	<ul> <li>PARTICIPANT &gt; PARTICIPANT &gt; Entity Identifier</li> </ul>
	Represented in CDA using XPath notation as:
	<ul> <li>/ClinicalDocument/participant/associatedEntity/associatedPerson/ext :asE ntityIdentifier</li> </ul>

027997	Primary healthcare provider organisation workplace address
	If instantiating the primary healthcare provider, the document <b>SHALL</b> contain one and only one value for healthcare provider organisation's workplace address and that address is an Australian address.
	Represented as the following data element if the primary healthcare provider is instantiated as a person:
	<ul> <li>PARTICIPANT &gt; PARTICIPANT &gt; PERSON OR ORGANISATION OR DEVICE &gt; PERSON &gt; EMPLOYMENT DETAIL &gt; EMPLOYER ORGANISATION &gt; ORGANISATION &gt; ADDRESS</li> </ul>
	Represented as the following data element if the primary healthcare provider is instantiated as an organisation:
	<ul> <li>PARTICIPANT &gt; PARTICIPANT &gt; ADDRESS</li> </ul>
	Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as a person, as:
	<ul> <li>/ClinicalDocument/participant/associatedEntity/associatedPerson/ext :asEmployment/ext:employerOrganization/asOrganizationPartOf/wh oleOrgani zation/addr</li> </ul>
	Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as an organisation, as:
	/ClinicalDocument/participant/associatedEntity/addr Trace: 26604
Priority	Conditional
Additional notes	Implementers should note that this requirement effectively makes the "Employment Detail" section mandatory.
028029	Primary healthcare provider role
	If instantiating the primary healthcare provider (/ClinicalDocument/participant/functionCode/@code="PCP"), the document <b>MAY</b> contain an absent value for the professional role. The professional role <b>SHALL NOT</b> be an abnormal value, represented as the following data element:
	PARTICIPANT > Role
	Represented in CDA using XPath notation as:
	/ClinicalDocument/participant/associatedEntity/code
Priority	Optional
Additional notes	Refer to Appendix B.4 Exceptional Values in the Core Level One Clinical Document Structured Content Specification for the permitted absent values. These absent values apply to primary healthcare provider role as a person and an organisation.

# 3 Known issues

27991 does not reflect the business requirement but instead is more consistent with previous approaches to addresses and the use.

# Acronyms

Acronym	Description
CDA	Clinical Document Architecture
CSP	Contracted service provider
IHI	Individual Healthcare Identifier
IHTSDO	International Health Terminology Standards Development Organisation
MIME	Multipurpose Internet Mail Extensions
OID	Object identifier
PSML	Pharmacist Shared Medicine List

## References

- [AGENCY2018a] Common Conformance Profile for Clinical Documents v1.7, Australian Digital Health Agency, 2018 https://developer.digitalhealth.gov.au/resources/clinical-documentscommon-conformance-profile-v1-7
- [AGENCY2018b] Core Level One Clinical Document Structured Content Specification v1.1, Australian Digital Health Agency, 2018 https://developer.digitalhealth.gov.au/resources/core-levelone-structured-content-specification-v1-1
- [AGENCY2018c] Core Level One Clinical Document CDA Implementation Guide v1.1, Australian Digital Health Agency, 2018 <u>https://developer.digitalhealth.gov.au/resources/core-level-one-cda-implementation-guide-v1-1</u>