



Australian Government
Australian Digital Health Agency



Pharmacist Shared Medicines List My Health Record Conformance Profile

31 March 2020 v1.1.1

Approved for external use

Document ID: DH-2926:2020

Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000
Telephone 1300 901 001 or email help@digitalhealth.gov.au
www.digitalhealth.gov.au

Acknowledgements

Council of Australian Governments

The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

HL7 International

This document includes excerpts of HL7™ International standards and other HL7 International material. HL7 International is the publisher and holder of copyright in the excerpts. The publication, reproduction and use of such excerpts is governed by the [HL7 IP Policy](#) and the HL7 International License Agreement. HL7 and CDA are trademarks of Health Level Seven International and are registered with the United States Patent and Trademark Office.

Disclaimer

The Australian Digital Health Agency (“the Agency”) makes the information and other material (“Information”) in this document available in good faith but without any representation or warranty as to its accuracy or completeness. The Agency cannot accept any responsibility for the consequences of any use of the Information. As the Information is of a general nature only, it is up to any person using or relying on the Information to ensure that it is accurate, complete and suitable for the circumstances of its use.

Document control

This document is maintained in electronic form and is uncontrolled in printed form. It is the responsibility of the user to verify that this copy is the latest revision.

Copyright © 2020 Australian Digital Health Agency

This document contains information which is protected by copyright. All Rights Reserved. No part of this work may be reproduced or used in any form or by any means – graphic, electronic, or mechanical, including photocopying, recording, taping, or information storage and retrieval systems – without the permission of the Australian Digital Health Agency. All copies of this document must include the copyright and other information contained on this page.

OFFICIAL

Document information

Key information

Owner	General Manager, Technology Delivery and Projects
Contact for enquiries	Australian Digital Health Agency Help Centre
Phone	1300 901 001
Email	help@digitalhealth.gov.au

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.

Table of contents

1	Introduction	5
1.1	Purpose	5
1.2	Intended audience	5
1.3	Scope.....	6
1.4	Overview	6
2	Pharmacist Shared Medicines List	7
2.1	Relevant specifications	7
2.2	Objects of conformance.....	7
2.3	Conformance criteria for producing systems	8
2.3.1	Application of Core Level One Clinical Document specifications	11
3	Known issues.....	19
	Acronyms	20
	References.....	21

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.

2.2 Objects of conformance

028153	<p>Allowed types of producers</p> <p>PSML clinical documents MAY be produced by:</p> <ul style="list-style-type: none"> • clinical information systems; and • 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	<p>Disallowed types of producers</p> <p>A PSML SHALL NOT be produced by a:</p> <ul style="list-style-type: none"> • registered consumer portal • registered repository • registered portal operator (mobile gateway), or • registered provider portal.
Priority	Mandatory

024569	<p>Disallowed types of producers</p> <p>A PSML SHALL NOT be produced by a:</p> <ul style="list-style-type: none"> • registered consumer portal • registered repository • registered portal operator (mobile gateway), or • registered provider portal.
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.

2.3 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	<p>Levels of conformance</p> <p>A PSML sent to the My Health Record system SHALL conform to the requirements for conformance level 1A as defined in the <i>Common Conformance Profile for Clinical Documents</i> [AGENCY2018a].</p>
Priority	Mandatory
028034	<p>Content of PSML</p> <p>The producing system SHALL have the capability to include in the document all medicines the patient record states an individual is known to be taking.</p>
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	<p>Medicine item</p> <p>If the producing system authors the PSML PDF, then the producing system SHALL include the medicine item in the attached PSML PDF as either:</p> <ul style="list-style-type: none"> • 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 SHALL 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 SHOULD 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 If the producing system authors the PSML PDF, then the producing system SHOULD include the authoring healthcare organisation's name in 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 SHOULD 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 SHOULD 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.

028154	Dose Administration Aids Software for Dose Administration Aids SHALL 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 SHALL NOT 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 SHALL NOT 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 SHOULD 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 SHALL contain one and only one personal identifier and that identifier SHALL be an Individual Healthcare Identifier (IHI).
Priority	Mandatory
027991	Subject of care address When instantiating the subject of care, the document SHALL contain: <ul style="list-style-type: none"> • an address (of any type), OR • a nullflavor (of any type) • or both, BUT NOT • an address (of any type) AND an MSK nullflavor.
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 AND 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 SHALL 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	<p>Document author organisation name</p> <p>When instantiating the document author, the document SHALL contain one and only one organisation name represented as:</p> <ul style="list-style-type: none"> Document Author > Participant > Person or Organisation or Device > Person > Employment Detail > Employer Organisation > Organisation > Organisation Name <p>Represented via the following XPATH:</p> <ul style="list-style-type: none"> /ClinicalDocument/author/assignedAuthor/assignedPerson/ext:asEmployment/ext:employerOrganization/asOrganizationPartOf/wholeOrganization/name
Priority	Mandatory
Additional notes	Implementers should note that this requirement effectively makes the “Employment Detail” section mandatory.
027993	<p>Document author workplace address</p> <p>When instantiating the document author, the document SHALL contain one and only one value for healthcare provider individual’s workplace address and that address is an Australian address.</p>
Priority	Mandatory
Additional notes	The document MAY contain other non-workplace addresses. See requirement 024982.
028630	<p>Document Author Entity Identifier value</p> <p>When instantiating the document author, the document SHALL contain one and only one personal identifier that is a Healthcare Provider Identifier for Individual (HPI-I), otherwise it SHALL have a value that identifies the document author, and that value SHALL NOT be a nullflavor.</p>
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	<p>Document author organisation identifier</p> <p>When instantiating the document author, the document SHALL contain one and only one organisation identifier and that identifier is a Healthcare Provider Identifier for Organisation (HPI-O).</p>
Priority	Mandatory

028068	<p>Inclusion of PDF attachment</p> <p>The document SHALL contain one and only one PSML document that reflects the original PSML document.</p> <p>The PSML document SHALL be a PDF packaged attachment.</p>
Priority	Mandatory
Additional notes	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • encryption • password protection • printing or copying restriction • embedded fonts (as not all PDF viewers support them).
028069	<p>Referencing PSML PDF attachment</p> <p>The document SHALL contain the PDF (see requirement 028068) in ENCAPSULATED DATA with</p> <p>“templateID/@root=“1.2.36.1.2001.1001.101.102.16883”</p> <p>under section with</p> <p>“templateID/@root=“1.2.36.1.2001.1001.101.101.16886”.</p>
Priority	Mandatory
Additional notes	<p>The document may contain other attachments (e.g. logos) that do not contain a PSML or any other medicines information.</p> <p>The requirement applies only to attachments that include PSML medicines.</p>
027998	<p>PDF attachment MIME type</p> <p>When instantiating a PDF attachment, the MIME type of the attachment SHALL be of .pdf application/pdf MIME type.</p>
Priority	Mandatory
Additional notes	<p>This requirement overrides Requirement 023741 in the Clinical Documents Common Conformance Profile.</p>

027999	<p>Document type</p> <p>When instantiating the document type, the software SHALL use:</p> <ul style="list-style-type: none"> the code “56445-0” in the code attribute of the code element of the clinical document; the OID in the codeSystem attribute of the code element of the clinical document SHALL be “2.16.840.1.113883.6.1”; and the title element value of the clinical document SHALL be “Pharmacist Shared Medicines List”.
Priority	Mandatory
028000	<p>Clinical document template identifier</p> <p>When instantiating the templateid the software SHALL ensure that one instance of the clinical document:</p> <ul style="list-style-type: none"> the root attribute of the templated element SHALL be “1.2.36.1.2001.1001.100.1002.237”; and the extension attribute of the templated 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	<p>Confirm author's personal electronic communication details to be included</p> <p>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 SHALL NOT be automatically included unless stated otherwise.</p>
Priority	Conditional

024980	<p>Confirm author's personal electronic communication details to be included</p> <p>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 SHALL NOT be automatically included unless stated otherwise.</p>
---------------	--

Additional notes	<p>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.</p> <p>The software can also demonstrate conformance by not capturing the individual's personal electronic communication details in the CIS.</p>
-------------------------	--

024982	<p>Confirm author's personal address to be included</p> <p>If the producing system captures the personal address of the document author, the individual personal address SHALL NOT be automatically included unless stated otherwise.</p>
---------------	---

Priority	Conditional
-----------------	-------------

Additional notes	<p>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.</p> <p>The software can also demonstrate conformance by not capturing the individual's personal address details in the CIS.</p>
-------------------------	--

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	<p>Primary healthcare provider</p> <p>The document SHALL contain at most one primary healthcare provider. The primary healthcare provider SHALL have PARTICIPANT (/ClinicalDocument/participant) instantiated with a typeCode of "PART" and a functionCode of "PCP":</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/@typeCode="PART" • /ClinicalDocument/participant/functionCode/@code="PCP".
---------------	---

Priority	Mandatory
-----------------	-----------

<p>028031</p>	<p>Primary healthcare provider organisation name</p> <p>If instantiating the primary healthcare provider as a person, the document SHALL contain one and only one organisation name represented as the following data element:</p> <ul style="list-style-type: none"> • PARTICIPANT > PARTICIPANT > PERSON OR ORGANISATION OR DEVICE > PERSON > EMPLOYMENT DETAIL > EMPLOYER ORGANISATION > ORGANISATION > Organisation Name <p>Represented in CDA using XPath notation as:</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/associatedEntity/associatedPerson/ext:asEmployment/ext:employerOrganization/asOrganizationPartOf/wholeOrganization/name
<p>Priority</p>	<p>Conditional</p>
<p>Additional notes</p>	<p>Implementers should note that this requirement effectively makes the “Employment Detail” section mandatory.</p>
<p>028032</p>	<p>Primary healthcare provider organisation identifier</p> <p>If instantiating the primary healthcare provider, the document SHOULD contain a Healthcare Provider Identifier for Organisation (HPI-O) as an organisation identifier.</p> <p>Represented as the following data element if the primary healthcare provider is instantiated as a person:</p> <ul style="list-style-type: none"> • PARTICIPANT > PARTICIPANT > PERSON OR ORGANISATION OR DEVICE > PERSON > EMPLOYMENT DETAIL > EMPLOYER ORGANISATION > ORGANISATION > Entity Identifier <p>Represented as the following data element if the primary healthcare provider is instantiated as an organisation:</p> <ul style="list-style-type: none"> • PARTICIPANT > PARTICIPANT > Entity Identifier <p>Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as a person, as:</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/associatedEntity/associatedPerson/ext:asEmployment/ext:employerOrganization/asOrganizationPartOf/wholeOrganization/ext:asEntityIdentifier <p>Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as an organisation, as:</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/associatedEntity/scopingOrganization/asOrganizationPartOf/wholeOrganization/ext:asEntityIdentifier
<p>Priority</p>	<p>Recommended</p>

028033	<p>Primary Healthcare provider individual identifier</p> <p>If instantiating the primary healthcare provider as a person, the document SHOULD contain a Healthcare Provider Identifier for Individual (HPI-I) as a person identifier represented as the following data element:</p> <ul style="list-style-type: none"> • PARTICIPANT > PARTICIPANT > Entity Identifier <p>Represented in CDA using XPath notation as:</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/associatedEntity/associatedPerson/ext:asEntityIdentifier
Priority	Recommended
027997	<p>Primary healthcare provider organisation workplace address</p> <p>If instantiating the primary healthcare provider, the document SHALL contain one and only one value for healthcare provider organisation’s workplace address and that address is an Australian address.</p> <p>Represented as the following data element if the primary healthcare provider is instantiated as a person:</p> <ul style="list-style-type: none"> • PARTICIPANT > PARTICIPANT > PERSON OR ORGANISATION OR DEVICE > PERSON > EMPLOYMENT DETAIL > EMPLOYER ORGANISATION > ORGANISATION > ADDRESS <p>Represented as the following data element if the primary healthcare provider is instantiated as an organisation:</p> <ul style="list-style-type: none"> • PARTICIPANT > PARTICIPANT > ADDRESS <p>Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as a person, as:</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/associatedEntity/associatedPerson/ext:asEmployment/ext:employerOrganization/asOrganizationPartOf/wholeOrganization/addr <p>Represented in CDA using XPath notation, if the primary healthcare provider is instantiated as an organisation, as:</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/associatedEntity/addr <p>Trace: 26604</p>
Priority	Conditional
Additional notes	Implementers should note that this requirement effectively makes the “Employment Detail” section mandatory.

028029	<p>Primary healthcare provider role</p> <p>If instantiating the primary healthcare provider (/ClinicalDocument/participant/functionCode/@code="PCP"), the document MAY contain an absent value for the professional role. The professional role SHALL NOT be an abnormal value, represented as the following data element:</p> <ul style="list-style-type: none"> • PARTICIPANT > Role <p>Represented in CDA using XPath notation as:</p> <ul style="list-style-type: none"> • /ClinicalDocument/participant/associatedEntity/code
Priority	Optional
Additional notes	<p>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.</p>

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
- [AGENCY2018b] *Core Level One Clinical Document Structured Content Specification v1.1*, Australian Digital Health Agency, 2018
- [AGENCY2018c] *Core Level One Clinical Document CDA Implementation Guide v1.1*, Australian Digital Health Agency, 2018