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Patient Medicines History Conformance Profile

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1 Introduction

1.1 Patient Medicines History Overview

The Patient Medicines History (PMH) enables authorised healthcare providers and consumers to access a consolidated view of a consumer's prescription and dispense history through a secure, consent-based service.

The PMH has been developed to improve medicines safety by reducing information gaps, supporting continuity of care, and providing timely access to medicines information across healthcare settings. By making prescription and dispense information more readily available, PMH supports safer clinical decision-making and more coordinated patient care.

The PMH provides a consolidated view of medicines information but does not change the core clinical processes of prescribing or dispensing medicines. Participation in PMH is consumer-controlled, with access to medicines history information governed by consent, privacy, and access management controls to ensure it is only available to authorised users for permitted purposes.

The PMH forms part of the broader national digital health ecosystem and builds on existing medicines safety and digital health infrastructure. It uses prescription and dispense information sourced through the National Prescription Delivery Service (NPDS) to provide a consolidated and timely view of a consumer's medicines history.

The PMH ecosystem includes prescribing systems, dispensing systems, consumer-facing applications, and intermediary services that exchange medicines information with the PMH Application Programming Interface (PMH API) using agreed standards and interfaces. These systems must operate in a secure, reliable, and interoperable manner to support the accurate and timely sharing of medicines history information.

1.2 Purpose

This document defines the functional and non-functional requirements for the PMH API and provides the basis for assessing conformance of the PMH API. The requirements support the secure, reliable and interoperable exchange of medicines history information and the safe operation of the PMH ecosystem.

Requirements applicable to systems that connect to the PMH API, including prescribing systems, dispensing systems, consumer-facing applications and intermediaries, are defined in the relevant PMH Connecting Systems Conformance Profiles.

1.3 Intended audience

This document is primarily intended for organisations that develop, implement, maintain, operate, or support the PMH API.

The document may also be of interest to organisations that develop, implement, maintain or support systems that connect to the PMH API, including prescribing systems,

dispensing systems, consumer-facing applications, and intermediaries. These stakeholders may use this document to understand the services, interfaces, behaviours, and requirements of the PMH API with which their systems interact.

The document may also be of interest to the Australian Digital Health Agency, the Department of Health, Disability and Ageing, software vendors, healthcare organisations, policy makers, regulators, and other stakeholders involved in medicines safety and digital health initiatives.

2 Scope

This document defines the functional and non-functional requirements for the Patient Medicines History (PMH) API. It applies to the PMH API and the services it provides to support the secure, reliable, and interoperable exchange of medicines history information within the PMH ecosystem.

This document defines requirements relating to:

- collection, storage, and management of medicines history information by the PMH API
- access to medicines history information through the PMH API
- consent, access management, privacy, security, and interoperability controls implemented by the PMH API
- interfaces between the PMH API and participating systems.

This document does not:

- define requirements for prescribing systems, dispensing systems, consumer-facing applications, or intermediaries
- define the conformance requirements of the National Prescription Delivery Service (NPDS)
- define operational, commercial or usability requirements
- define certification, participation or conformance requirements for external national infrastructure or services
- cover functionality unrelated to the PMH API.

Requirements applicable to systems that connect to the PMH API are defined in the relevant PMH Connecting Systems Conformance Profiles.

Software developers, implementers, and operators remain responsible for complying with applicable Commonwealth, state and territory legislation, regulations, standards, policies, and guidelines relevant to their participation in the PMH ecosystem.

3 Conformance Requirements

3.1 Conformance Requirements Approach

This Conformance Profile defines the functional and non-functional requirements that the PMH API must meet to support the secure, reliable, and interoperable exchange of medicines history information.

The requirements are intended to:

- support the secure collection, storage, management, and exchange of medicines history information
- support privacy, security, safety, and system integrity
- promote interoperability between the PMH API and connecting systems
- support compliance with applicable legislative, regulatory and policy obligations.

Requirements follow a standard form, utilising the following language:

SHALL: When appearing in a conformance requirement, the verb SHALL indicates a mandatory requirement. Its negative form SHALL NOT indicates a prohibition.

SHOULD: When appearing in a conformance requirement, the verb SHOULD indicates a recommendation. Its negative form SHOULD NOT indicate an option that should not be supported.

MAY: When appearing in a conformance requirement, the verb MAY indicates an optional requirement.

Software developers, implementers, and operators are responsible for ensuring their solutions comply with applicable Commonwealth, state and territory legislation, regulations, standards, policies, and guidelines relevant to their participation in the PMH ecosystem.

4 Conformance requirements for Patient Medicines History (PMH) API

This section describes conformance requirements specifically for systems participating in the collection, storage, management, and access of Patient Medicines History.

4.1 Patient Medicines History (PMH)

The PMH is a national service that enables authorised healthcare providers to access a patient's medicine history, subject to patient consent.

There is an expectation for the PMH and participating systems to interoperate and exchange information in a non-disruptive and harmonious manner and the degree of co-operation between systems is a routine aspect of conformance testing.

This profile refers to the following concepts:

- *A Subject of Care (SoC): The person for whom the medicines shown in the Patient Medicines History are intended.*
- *A Carer: An authorised individual who can register for and interact with the SoC's PMH as if they were the SoC (e.g., a parent registering and managing PMH for their children)*

Primary Contact Point for PMH Notifications

This profile requires a PMH to have a single primary electronic contact point, such as a mobile number or email address. This contact point can belong to the person receiving care (SoC) or their representative (who is supporting the SoC).

The SoC or their representative can choose who this contact point will be to receive PMH notifications.

4.1.1 NPDS Integration

Reference	Requirement
PMH-345	The system SHALL only receive prescription and dispense information (including original or repeat authorisation) for a SoC where the SoC has consented to PMH participation and has an active PMH. <i>Note: the PMH must not be in possession of the SoC's prescription or dispense information unless the SoC consents by activating their PMH.</i> <i>Note: prescription and dispense information received for a PMH that is NOT activated must be discarded and not retained.</i>

Reference	Requirement
PMH-346	The system SHALL ensure that the status of all prescribing and dispensing records in the PMH are synchronised with, and accurately represent the statuses in the NPDS, including any updates to active, ceased, cancelled, expired, and dispensed statuses.

4.1.2 Authentication and Authorisation

Reference	Requirement
PMH-343	The system SHALL NOT transact with a non-conformant connecting system. <i>Note: the connecting systems transacting with PMH are the NPDS, prescribing systems, dispensing systems, and consumer-facing /intermediaries.</i>
PMH-938	The system SHALL validate digital certificates. <i>Note: see Appendix B - Implementation Advice for further guidance</i>
PMH-342	The system SHALL NOT accept electronic prescription or dispense information from any source other than the NPDS.

4.1.3 Registration and Management

PMH Assisted Registration and Management: The PMH assisted registration and management feature allows a SoC or their representative to register for a PMH with the support of an authorised user of a PMH conformant prescribing or dispensing system. Authorised users may assist with PMH registration and ongoing PMH management activities only when the SoC or their representative has provided relevant consent.

Reference	Requirement
PMH-210	The system SHALL support PMH assisted registration functionality provided by connecting prescribing and dispensing systems

Reference	Requirement
PMH-210A	For a PMH registration, the system SHALL receive PMH registration information from a connecting prescribing, dispensing or consumer-facing application/intermediary system and SHALL only store the following SoC's information in the PMH: • IHI number • legal family name • legal given name (if available) • date of birth (DOB) • gender • Medicare card number and IRN (if available) • DVA number (if available) • residential address (if available) and SHALL store one and only one primary contact for the SoC's PMH, as nominated by the SoC or their representative through the PMH registration process, for administrative purposes: • mobile number; or • email address. <i>Note: the above attributes align to the attributes used by the HI Service when there is a need to validate an IHI.</i> <i>Note: it is important that the PMH stores the SoC's data as communicated by connecting systems to maintain data integrity across systems.</i> <i>Note: see also PMH-225 and PMH-235 for carers.</i> <i>Note: the SoC or their representative needs to nominate, through the PMH assisted registration process, a primary contact that can receive PMH notifications.</i>
PMH-265	When the system receives a SoC's details for PMH registration and is performing a PMH registration, the system SHALL obtain and record the SoC's or their Carer's consent confirming their agreement to proceed with PMH registration before completing the PMH registration for the SoC. <i>Note: a nominated primary contact through the PMH assisted registration process is used to obtain PMH registration consent.</i>
PMH-265A	When obtaining consent for PMH registration, the system SHALL provide the SoC or their representative access to the PMH registration Terms & Conditions and applicable privacy notice. <i>Note: this ensures that the SoC or their representative is informed of how their personal data will be collected, used, and managed by the PMH.</i>

Reference	Requirement
PMH-225	The system SHALL support the registration of at least one Carer on the SoC's PMH and only store the following Carer's information in the PMH: • family name • given name (if available) • residential address (if available) • relationship to SoC (if available) and MAY capture the Carer's contact details for administrative purposes, including: • mobile number • email address. <i>Note: the connecting prescribing or dispensing system will provide Carer's details to the PMH.</i> <i>Note: if the Carer is an organisation (e.g., residential aged care facility) then PMH-235 applies.</i> <i>Note: the system must record the above attributes as separate attributes (i.e. not as a single text field) as future architecture may require this information to be discrete and ready to be validated for identity management purposes.</i>
PMH-235	The system SHALL support the registration of an organisation name and details as a Carer for the SoC and only store the following organisation information in the PMH: • organisation name • organisation address (if applicable) • point of contact name (if available) and MAY capture at least one of the contact details of the carer organisation below, for administrative purposes: • mobile number • email address. <i>Note: the connecting prescribing or dispensing system will provide the Carer's details to the PMH.</i> <i>Note: community care organisations, such as a residential care facility, with the SoC's permission, can be nominated as a Carer for a SoC receiving care at that organisation. This enables the organisation to receive electronic notifications and provide site consents on behalf of the SoC.</i> <i>Note: the attributes specified in PMH-225 do not apply to organisations as a Carer.</i>

Reference	Requirement
PMH-250	The system SHALL support the subsequent update of the SoC's and Carer's information that is registered in the PMH. <i>Note: the connecting prescribing or dispensing system will provide updated details to the PMH.</i> <i>Note: the term 'update' includes add, remove, and modify operations.</i>
PMH-355	The system SHALL reject the request to delete, remove, or erase the nominated primary contact details associated with a PMH record. <i>Note: the PMH supports the editing/updating of primary contact information.</i>
PMH-240	When the system receives the SoC's details for PMH registration, the system SHALL store one and only one primary contact for the SoC's PMH, as nominated by the SoC or their representative through the PMH assisted registration process. <i>Note: the SoC or their representative needs to nominate, through the PMH assisted registration process, a primary contact that can receive PMH notifications.</i>

4.1.4 Viewing

PMH Viewing for healthcare professionals Access to a SoC's PMH is controlled by the SoC or their Carer through the PMH consent process. Authorised users of PMH conformant prescribing and dispensing systems may request access to view a SoC's PMH. Access is provided only where the SoC has an active PMH and the relevant consent requirements have been met.

PMH Viewing for SoC or Carer: PMH viewing allows a SoC or Carer to access medicines history information available through the PMH using a PMH conformant consumer-facing application. Consumer-facing applications may connect directly to the PMH or through a PMH conformant intermediary. Access is subject to successful PMH linking and applicable consent and access management controls.

Reference	Requirement
PMH-275	The system SHALL provide a mechanism for the connecting prescribing and dispensing system to determine if the SoC has an active PMH.
PMH-295	If the SoC has an active PMH record, the system SHALL provide a mechanism for the connecting prescribing or dispensing system to determine whether the healthcare provider organisation has been given site consent to access the SoC's PMH.

Reference	Requirement
PMH-305	When a site without active site consent requests access, the system SHALL obtain and record consent from the primary contact for the PMH, before granting the site access to a SoC's PMH. The consent request SHALL include: - the name of the healthcare provider organisation requesting access (mandatory) - the name of the individual healthcare provider requesting access (optional). <i>Note: the healthcare provider organisation name should enable the primary contact to identify the organisation requesting access.</i>
PMH-280	The system SHALL provide a mechanism to view a SoC's PMH from a connecting prescribing or dispensing system only if all the following conditions are met: - the SoC has a PMH and - the healthcare provider has site consent to access the SoC's PMH.
PMH-285	The system SHALL provide a mechanism to view a SoC's PMH from a connecting consumer-facing application/intermediary only if all the following conditions are met: - the SoC has an active PMH record; and - the requesting consumer-facing application/intermediary has been granted access through the PMH linking process.
PMH-315	The system SHALL on request provide to the PMH conformant connecting system all available prescription and dispense record information in accordance with the PMH FHIR Implementation Guide. <i>Note: for more information on the PMH FHIR IG, see https://ig.mypmh.com.au/</i>

4.1.5 PMH Linking

PMH linking enables a SoC or Carer to access and manage a PMH through a conformant consumer-facing application. To establish access, the consumer-facing application user account must be linked to the SoC's PMH using a single-use 'PMH Linking Code'. A PMH Linking Code may be issued by an authorised user of a conformant prescribing or dispensing system following verification of the SoC's or carer's identity.

Reference	Requirement
PMH-1200	The system SHALL provide a mechanism for the connecting prescribing or dispensing system to request a unique, single-use PMH linking Code. <i>Note: a connecting system may request multiple single-use PMH linking codes to support linking to multiple consumer-facing applications.</i>

Reference	Requirement
PMH-1200C	The system SHALL ensure that each PMH Linking Code generated for a PMH is unique and is not reused.
PMH-1201	The system SHALL verify that a PMH Linking Code is current and valid before granting an application user account access to a SoC's PMH.
PMH-941	The system SHALL provide a mechanism for a connecting prescribing or dispensing system to discontinue a Subject of Care's (SoC's) Patient Medicines History (PMH) and SHALL ensure that the discontinued PMH is no longer accessible and all associated PMH data is removed from the PMH repository. <i>Note: the SoC or their representative will be required to complete a new PMH registration if they subsequently wish to establish a PMH.</i>

4.1.6 Logging and Reporting

Reference	Requirement
PMH-1400	The system SHALL retain logs in accordance with relevant legislation and regulations.
PMH-1425	The system SHALL, on request, generate a file or files that contain the information captured in the logs. <i>Note: this requirement permits the generation of a file or files that can be shared or sent to authorised requestors.</i>
PMH-410A	The system SHALL retain a log of all PMH management and access events, including: • registration • deregistration • consent from the SoC • site-consent changes • updates to the SoC or their representative's information • consumer-facing application linking. For each PMH management event, the log SHALL include: • date and time (including time zone) of PMH management event • SoC's unique identifier (if available) • type of PMH management event. For connecting prescribing and dispensing systems, the log SHALL include: • organisation or site ID • conformance ID of the requesting system.

Reference	Requirement
PMH-410B	The system SHALL retain a log of all medicine history searches for a Subject of Care (SoC). For each medicine history access event, the log SHALL include: • date and time (including time zone) of the event • SoC unique identifier • type of access event • details of the information requested • identifier(s) used to perform the transaction. For transactions initiated by a prescribing or dispensing system, the log SHALL include: • organisation or site identifier • conformance ID of the requesting system. <i>Note: the identifier recorded for a medication information access event may vary based on the transaction and may include an IHI, Subject of Care unique identifier, consent identifier, or another transaction-specific identifier used to retrieve the information.</i>

4.1.7 Cryptography

Reference	Requirement
PMH-1015	The system SHALL encrypt electronic prescription information assets in transit and at rest, using Australian Signals Directorate (ASD) Approved Cryptographic Algorithms. <i>Note: this includes all transmissions of electronic prescription information over public networks.</i>

4.1.8 Privacy

Reference	Requirement
PMH-25A	The system SHALL ensure that all collection, use, storage, and disclosure of personal and sensitive electronic prescription information adhere with Australian Privacy Principles (APP 6) within the Privacy Act 1988.

4 Acronyms and Abbreviations

Acronym/Abbreviation	Description
API	Application Programming Interface
APP	Australian Privacy Principles
ASD	Australian Signals Directorate
CAS	Conformance Assessment Scheme
CP	Conformance Profile
CTS	Conformance Test Specification
DOB	Date of Birth
DSPID	Delivery Service Prescription Identifier
GEP	General Electronic Prescription
HI Service	Healthcare Identifiers Service
IHI	Individual Healthcare Identifier
NASH	National Authentication Service for Health
NPDS	National Prescription Delivery Service
PKI	Public Key Infrastructure
PMH	Patient Medicines History
PMH API	Patient Medicines History API
SoC	Subject of Care

5 Glossary

Term	Meaning
Australian Digital Health Agency (the Agency)	The organisation responsible for developing, publishing, maintaining and administering the PMH Conformance Assessment Scheme, Conformance Profiles and Conformance Test Specifications.
Authorised user	An individual whose access to PMH-related system functions and operations is governed by role-based permissions and privileges within the system. Access is limited to activities appropriate to the individual's professional role and scope of practice. Examples of authorised users may include prescribers, pharmacists, nurses, dispense technicians, healthcare workers and system administrators performing activities authorised by the participating organisation.
Carer (in PMH context)	An authorised individual who can register for and interact with the SoC's PMH as if they were the SoC (e.g., a parent registering and managing PMH for their children).
Conformance	Demonstrated compliance of a software product with the applicable PMH Conformance Profile requirements.
Conformance assessment	The process used to determine whether a software product satisfies the applicable PMH Conformance Profile requirements.
Conformance Assessment Scheme (CAS)	The framework that describes the processes for establishing, assessing, and maintaining the conformance of software products participating in the PMH ecosystem.
Conformance Profile (CP)	A document that defines the functional and non-functional requirements applicable to a software system role participating in the PMH ecosystem.
Conformance Identifier (ID)	A unique identifier assigned to a software product version that has successfully completed the PMH conformance process. Conformance IDs are approved by the Agency and remain confidential.
Conformance Register	A publicly available record maintained by the Agency of software products that have successfully demonstrated conformance with the applicable PMH Conformance Profile requirements.
Conformance Test Specification (CTS)	A document containing the test cases, expected results and traceability information used to assess a software product against the applicable PMH Conformance Profile requirements.
Conformant consumer-facing application	A mobile or web application that has successfully demonstrated conformance with the applicable PMH requirements and enables consumers to access or manage their medicines history information and consent preferences.

Term	Meaning
Conformant dispensing system	A pharmacy dispensing software system that has successfully demonstrated conformance with the applicable PMH requirements. Dispensing systems may contribute to a consumer's medicines history through dispensing activities and, where authorised, access medicines history information via the PMH to support dispensing activities.
Conformant intermediary	A software system that has successfully demonstrated conformance with the applicable PMH requirements and facilitates access to PMH functionality on behalf of a consumer-facing mobile or web application.
Conformant prescribing system	A clinical software system used by authorised prescribers that has successfully demonstrated conformance with the applicable PMH requirements. Prescribing systems may contribute to a consumer's medicines history through prescribing activities and, where authorised, access medicines history information to support prescribing activities and clinical workflows.
Consumer	A SoC or SoC's representative
Delivery Service Prescription Identifier (DSPID)	Unique identifier that identifies the electronic prescription within the NPDS. If applicable, this identifier may change through the prescription lifecycle (e.g., one that points to original, one that points to repeat authorisation). The DSPID may also be referred to as SCID.
General electronic prescription (GEP)	Electronic prescription created by conformant general electronic prescribing systems for community, outpatient or discharge prescriptions and submitted to the NPDS. A GEP is a legal instrument that includes all medicine details the pharmacy needs to supply the medicine.
Healthcare organisation	A healthcare organisation authorised to access PMH information in accordance with applicable consent and access controls.
Individual Healthcare Identifier (IHI)	An Individual Healthcare Identifier (IHI) is a unique number used to identify an individual for health care purposes, in Australia.
MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
National Prescription Delivery Service (NPDS)	The national service that receives and manages electronic prescription, dispense information, and provides the medicines history information made available through the PMH API.
National Prescription Delivery Service (NPDS) Operator	The operator of the NPDS who provides managed services for the operations of Electronic Prescribing.
Patient Medicines History (PMH)	A secure, consent-based capability that enables authorised healthcare providers and consumers to access a consolidated view of a patient's prescription and dispense history.

Term	Meaning
Patient Medicines History API (PMH API)	A secure application programming interface that enables authorised conformant systems to exchange medicines history information with PMH in accordance with applicable consent, privacy, and access management requirements.
PMH ecosystem	The systems, services and participants involved in accessing, managing, or exchanging medicines history information through PMH.
Personal and sensitive information	Personal information is information about an individual. Sensitive information is personal information that has a higher level of privacy protection than other personal information. See https://www.oaic.gov.au/privacy/guidance-and-advice/what-is-personal-information
PMH Linking Code	A unique, single-use code which enables the linking of a consumer-facing application user account to a SoC's PMH.
Prescription record	The required data elements are stored electronically in the NPDS in accordance with relevant legislation, regulations, and Conformance Profiles. Together, these data elements constitute a legal prescription and serve as the instrument for the supply of medicines, as well as for supporting clinical safety and operational processes.
Representative	An individual authorised by the Subject of Care to support them in receiving care.
SHALL	When appearing in a conformance requirement, the verb SHALL indicates a mandatory requirement. Its negative form SHALL NOT indicates a prohibition.
SHOULD	When appearing in a conformance requirement, the verb SHOULD indicates a recommendation. Its negative form SHOULD NOT indicate an option that should not be supported.
Site consent	Consent provided by a SoC or their representative that authorises a healthcare provider organisation to access the SoC's PMH to support management or viewing.
Subject of Care (SoC)	The individual whose medicines' history information is accessed or managed through the PMH.

Appendix A References

[ACSQHC2017] *National Guidelines for on-screen display of Medicines Information*, Australian Commission on Safety and Quality in Healthcare, December 2017

Appendix B Implementation Advice

Digital Certificate Validation	Implementation advice for the validation of PKI certificates and use of PKI Certificate Authorities (CAs): • It is recommended that software developers are using CAs and certificates which implements Certificate Transparency (CT), except when NASH certificates are used. • The National Authentication Service for Health (NASH) is a PKI that was established for healthcare in Australia and is highly recommended as a PKI solution, (refer https://www.servicesaustralia.gov.au/national-authentication-service-for-health). Useful links: • RFC5280: Technical detail for certificate validation (https://www.ietf.org/rfc/rfc5280.txt) • National Institute of Standards and Technology (NIST) provided resources for testing PKI implementations, including certificate validation and path checking https://csrc.nist.gov/projects/pki-testing
Encryption of data at rest	Use strong encryption to safeguard sensitive data, both when stored and when transmitted. All prescription and patient data must be protected with encryption algorithms and protocols approved by the Australian Government specifically the Australian Signals Directorate (ASD). Encryption is a foundational control to ensure that even if data is intercepted or stolen, it remains unintelligible. Mandatory encryption of health information is a de-facto requirement under many frameworks due to protection of data confidentiality and integrity.