



Australian Government
Australian Digital Health Agency

Electronic Prescribing Conformance Assessment Scheme

30 September 2026 v3.0

Approved

Document ID: DH-4417:2026

Acknowledgements

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

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 © 2026 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 Chief Digital Officer, Australian Digital Health Agency

Date of next review 30 June 2027

Contact for enquiries Australian Digital Health Agency Help Centre

Phone [1300 901 001](tel:1300901001)

Email help@digitalhealth.gov.au

Product or document version history

Product or document version	Date	Release comments
DRAFT for information 1.0	23 September 2019	Preliminary document released for external information
2.0	31 October 2019	Final document for external use
2.1	30 April 2020	Amended to permit the co-existence of multiple conformance profiles
DRAFT 3.0	30 June 2026	Uplifted draft for publication to accommodate changes in the Electronic Prescribing Conformance processes

Table of contents

Document information	3
Table of contents	4
1 Introduction	6
1.1 Background	6
1.2 Overview	6
1.3 Purpose	7
1.4 Objectives	7
1.5 Intended audience	7
1.6 Scope	7
1.7 Relevant documents	8
2 Electronic Prescribing Conformance Lifecycle	10
3 Conformance assessment overview	11
3.1 Conformance approach	11
3.2 Object of conformance testing	11
3.3 Conformance Register	14
3.4 Conformance ID	14
3.5 Services provided by the Agency	14
4 Conformance Profile overview	17
4.1 Conformance Profile Requirements	17
4.2 Conformance Profile maintenance and sunsetting	18
4.3 Gaps in Conformance Profiles	18
5 Conformance assessment approach	19
5.1 Understand Electronic Prescribing	19
5.2 Identification of EP System Role and applicable Conformance Profile	19
5.3 HI Service conformance pre-requisite	19
5.4 NPDS Integration testing pre-requisite	19
5.5 Finalise the conformance process	19
6 Conformance assessment process	21
6.1 Observed testing session	21
6.1.1 Conformance test specifications	21
6.1.2 Success criteria	22
6.2 Review, verify and validate test evidence	22
6.3 Feedback and supported issue resolution	22
6.4 Assess declaration of conformance and notify outcome	22
6.4.1 Declaring conformance	23
6.5 Include software system on conformance register	23
6.6 Production access granted	23

6.6.1	Conformance ID assertion.....	23
7	Ongoing validity of conformance	24
7.1	Obligations of re-testing	24
7.2	Conformance and EP system versioning	24
7.3	Validity period	25
7.4	Conformance breaches.....	25
7.5	Future state	26
	Acronyms and Abbreviations	27
	Glossary	28
	References	31

Tables and figures

Table 1.	Electronic prescribing systems and descriptions	12
Table 2.	Servies provided by the Agency	14
Table 3.	Electronic prescribing Conformance Profile and System role examples	17
Figure 1.	Electronic prescribing document framework	9
Figure 2.	Electronic Prescribing Conformance Lifecycle.....	10
Figure 3.	Overview of the electronic prescribing systems of the electronic prescribing ecosystem	12

1 Introduction

1.1 Background

Electronic prescribing is a foundational element of Australia's digital health transformation, enabling safer, more efficient, and connected medication management across the healthcare system. Since the first electronic prescription was issued on 6 May 2020 and nationwide implementation in 2021, adoption has grown rapidly. As of 31 December 2025, more than 447 million electronic prescriptions have been generated, demonstrating strong uptake and demand from both healthcare providers and consumers.

Electronic prescribing (EP) allows prescriptions to be created, transmitted, and dispensed digitally without the need for paper, using conformant systems supported by the NPDS. These prescriptions hold the same legal status as paper prescriptions and are supported by Commonwealth, state, and territory legislation, including the [National Health \(Pharmaceutical Benefits\) Regulations 2017](#)¹ and the [Electronic Prescriptions Information Technology Requirements Instrument 2019](#)².

1.2 Overview

As outlined in **Figure 1**, the Australian Digital Health Agency (the Agency) maintains the Electronic Prescribing Conformance Assessment Scheme (CAS) Framework, which operates in accordance with the [Electronic Prescriptions Information Technology Requirements Instrument 2019](#)³, under which the Agency is authorised to manage the CAS.

Under this Instrument, all information systems used for the preparation, transmission, and dispensing of electronic prescriptions must conform to the CAS Framework to obtain a valid conformance identifier.

The CAS provides the formal process for verifying system compliance with approved information technology requirements. Through the CAS, software systems are rigorously assessed and certified, ensuring they meet national standards and support the safe, reliable delivery of EP across Australia. Upon successful completion of these requirements, systems provide a valid Conformance identifier (Conformance ID) and are authorised to connect to the National Prescription Delivery Service (NPDS).

¹ Department of Health, Disability and Ageing, [National Health \(Pharmaceutical Benefits\) Regulations 2017](#), Department of Health, Disability and Ageing website, 2026, accessed 30 June 2026.

² Department of Health, Disability and Ageing, [Electronic Prescriptions Information Technology Requirements Instrument 2019](#), Department of Health, Disability and Ageing website, 2026, accessed 30 June 2026.

³ Department of Health, Disability and Ageing, [Electronic Prescriptions Information Technology Requirements Instrument 2019](#), Department of Health, Disability and Ageing website, 2026, accessed 30 June 2026.

1.3 Purpose

This document sets out the CAS, developed and maintained by the Agency in accordance with the [Electronic Prescriptions Information Technology Requirements Instrument 2019](#).⁴ It describes the process for assessing the conformance of systems involved in the prescribing, dispensing, transmission, and management of electronic prescriptions.

1.4 Objectives

The objectives of the CAS, together with the relevant Commonwealth and state or territory regulations, aims to provide users, regulators and consumers with an acceptable level of assurance that the software and systems used for EP are secure and safe to use.

1.5 Intended audience

The primary audience of this CAS document are organisations who currently, or intend to, develop or implement software systems for the prescribing, dispensing, transmission or management of electronic prescriptions and electronic prescription information in Australia.

In addition to this primary group of organisations, a broader audience exists, including the following government bodies: the Agency, the Department of Health, Disability and Ageing (the Department), Services Australia, Department of Veterans Affairs, Commonwealth, state and territory regulators responsible for legislation governing the prescribing and dispensing of electronic prescriptions in Australia

1.6 Scope

The scope of the CAS is to define the electronic prescribing conformance lifecycle approach and the processes for establishing and maintaining the conformance of software systems participating in EP in Australia. Refer to [Section 2, Electronic Prescribing Conformance Lifecycle](#) for further information.

The CAS does not describe any conformance activities in relation to the My Health Record System, the Healthcare Identifiers (HI) Service, the National Authentication Service for Health (NASH), Secure Messaging or the Pharmaceutical Benefits Scheme (PBS) Claiming Service (PBS Online). Where interaction with those systems is required by other software or systems participating in EP, the software or systems will be expected to comply with the certification requirements specific to the use of those systems.

⁴ Department of Health, Disability and Ageing, [Electronic Prescriptions Information Technology Requirements Instrument 2019](#)

1.7 Relevant documents

In accordance with the [Electronic Prescriptions Information Technology Requirements Instrument 2019](#)⁵, the CAS identifies and leverages a range of supporting documents relevant to EP. This document should be read in conjunction with other EP documents published by the Agency, as well as relevant Commonwealth, state, and territory legislation and regulations, standards, and guidelines, as illustrated in **Figure 1 below**.

The below references and links contain additional related artefacts:

- Artefacts within the [Electronic Prescribing Conformance Assessment Framework](#)⁶ and [Electronic Prescribing - Conformance Test Specifications](#)⁷
- Relevant state, territory and [Commonwealth legislative and policy instruments](#)⁸
- Pharmaceutical Benefits Scheme (PBS) artefacts provided by [Services Australia](#)⁹
- [Medicine Safety Standards](#)¹⁰ provided by the Australian Commission on Safety and Quality in Health Care

⁵ Department of Health, Disability and Ageing, [Electronic Prescriptions Information Technology Requirements Instrument 2019](#)

⁶ Australian Digital Health Agency, [Electronic Prescribing | Digital Health Implementer Hub](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.

⁷ Australian Digital Health Agency, [Electronic Prescribing – Conformance Test Specifications](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.

⁸ Department of Health, Disability and Ageing, [Legislative and policy framework](#), Department of Health, Disability and Ageing website, 2026, accessed 1 April 2026.

⁹ Services Australia, [Services Australia](#), Services Australia website, 2026, accessed 1 April 2026.

¹⁰ Australian Commission on Safety and Quality in Health Care, [Medication Safety Standards](#), Australian Commission on Safety and Quality in Health Care website, accessed 1 April 2026.

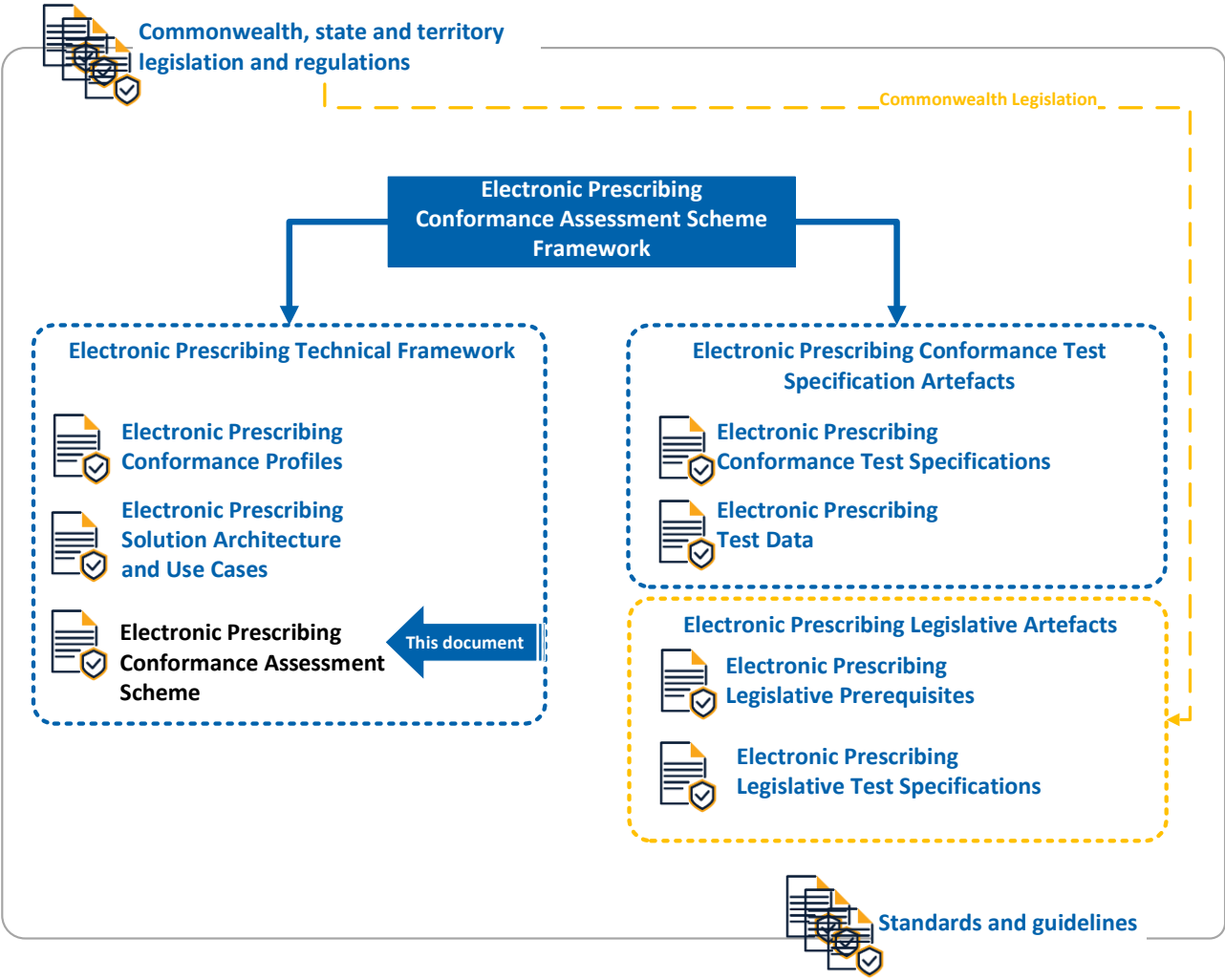


Figure 1. Electronic prescribing document framework

2 Electronic Prescribing Conformance Lifecycle

Figure 2 provides an overview of the EP system conformance lifecycle, showing the progression from design and testing through to conformance assessment, go-live, monitoring, sunsetting of conformance and potential breach management.

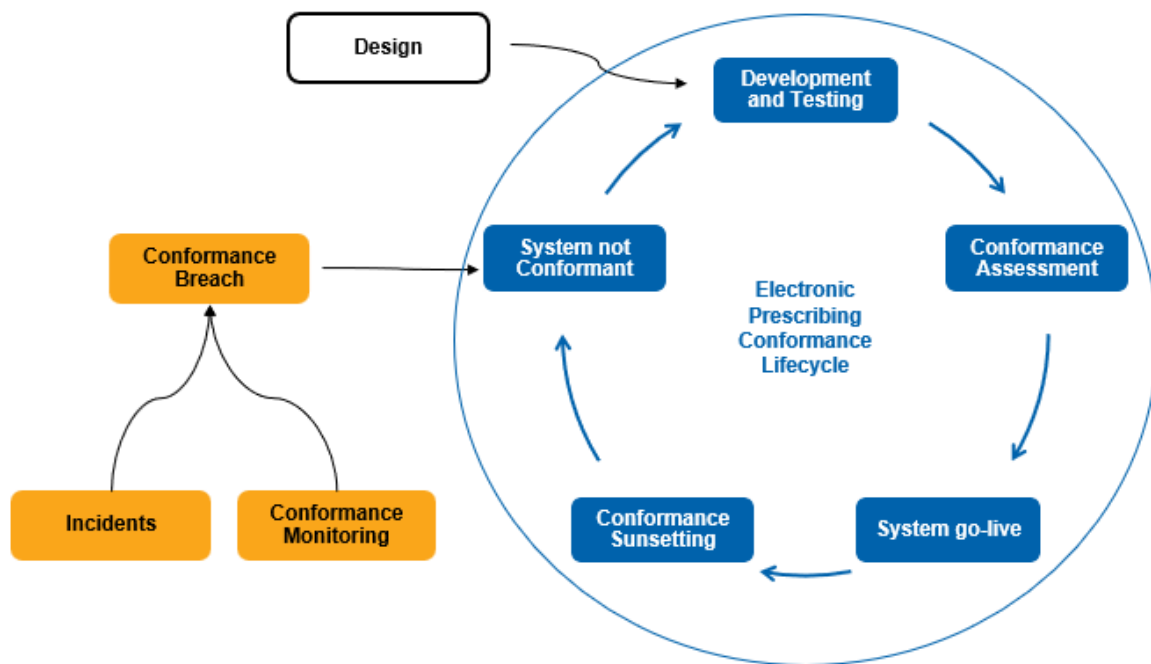


Figure 2. Electronic Prescribing Conformance Lifecycle

3 Conformance assessment overview

3.1 Conformance approach

Electronic prescribing use cases and conformance requirements have been developed to help software vendors create a software system that:

- Minimises risks to patient safety, privacy and cyber security
- Implements good practice for the prescribing, dispensing, transmission and management of electronic prescriptions and electronic prescription information.
- Complies with all applicable Commonwealth and Jurisdictional legislations and regulations.

Conformance provides one mechanism through which risks can be mitigated. Other mechanisms for risk mitigation may include, but are not limited to, Commonwealth and state and territory legislation and regulations, implementation guidelines, local policies or procedures, user education and training. Risk mitigation mechanisms other than conformance are out of scope for this document. Risks associated with deployment and implementation are also not covered within this document.

3.2 Object of conformance testing

The EP ecosystem comprises multiple systems that perform defined roles, as illustrated in **Figure 3** and described in **Table 1**. These systems constitute the objects of conformance testing under the CAS.

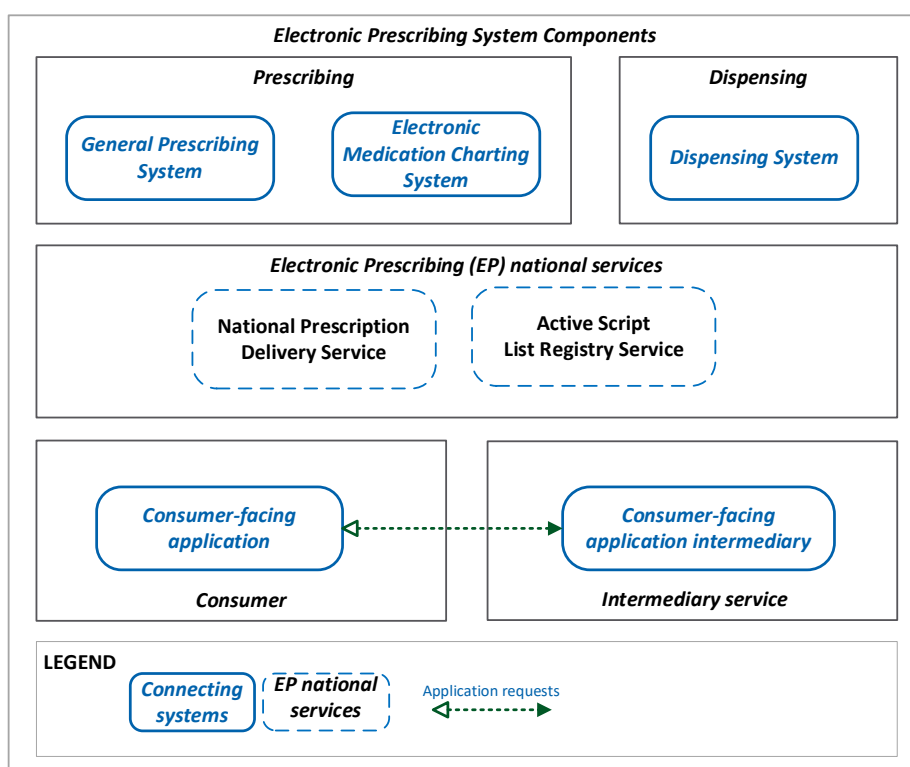


Figure 3. Overview of the electronic prescribing systems of the electronic prescribing ecosystem

A system, for example, an Electronic Medication Chart System (EMCS), may consist of a number of separate but interacting systems, such as a patient administration system and provider directory. In this case, the object of assessment refers to these separate interacting systems as a whole which make up an overall EP system.

Table 1. Electronic prescribing systems and descriptions

<i>System</i>	<i>Description</i>
Active Script List Registry (ASLR)	The ASLR is a national service that provides Active Script List (ASL) capability.
Conformant consumer-facing applications	A conformant consumer-facing application is an application that has been formally assessed for electronic prescribing conformance requirements, enabling it to be used by consumers to engage with electronic prescriptions. Consumer-facing applications provide users with the ability to manage electronic prescriptions via personal electronic devices. This may be a mobile or web application.
Conformant dispensing system	A conformant dispensing system is a pharmacy dispensing software system that has been formally assessed for electronic prescribing conformance requirements, enabling it to be used by authorised dispensers/pharmacists to access electronic prescriptions from the NPDS.
Conformant intermediary	A conformant intermediary is a system that has been formally assessed as passing all relevant electronic prescribing conformance requirements and serves as an intermediary for a consumer-facing application, enabling it to access all functionalities provided through/by the NPDS or ASLR.
Conformant general prescribing system	A conformant general prescribing system is a clinical prescribing software system that has been formally assessed for general electronic prescribing conformance requirements, enabling it to be used by authorised prescribers to generate and transmit general electronic prescription activities to the NPDS.
Conformant electronic medication charting system	A conformant electronic medication charting system is a clinical prescribing software system that has been formally assessed for electronic medication charting system conformance and legislative requirements, enabling it to be used by authorised prescribers to generate and transmit chart-based electronic prescription activities to the NPDS.

<i>System</i>	<i>Description</i>
National Prescription Delivery Service (NPDS)	The NPDS is a national service that enables electronic transfer of prescription information between conformant systems. It provides the mechanism to ensure all prescription information is communicated accurately and securely, supporting safe and efficient supply of medicines.

3.3 Conformance Register

The [EP Conformance Register](#)¹¹ is a publicly available record, published on the Agency's website, of EP software products that have been declared compliant with relevant legislation and conformance requirements. It provides visibility of conformant products to healthcare providers, implementers, and the software industry.

Conformance Register entries include system information such as the product name, provider, version, applicable Conformance Profile, and the registration commencement and end dates.

3.4 Conformance ID

A Conformance ID is a unique text string of up to 36 printable characters consisting of a text string representing the product name, a single character delimiter ('|') and an alphanumeric string representing the software product version. The Conformance ID is used to uniquely identify the version of the software system which achieved conformance.

Conformance IDs are declared to and approved by the Agency and remain confidential and supports the Agency's ability to control the software's authority to operate. Systems may only connect to the NPDS by asserting a current and valid Conformance ID listed on the Agency's Conformance Register. These IDs are also included in PBS electronic prescription data to enable Services Australia to verify PBS/Repatriation Pharmaceutical Benefits Scheme (RPBS) claims.

3.5 Services provided by the Agency

The Agency provides the following CAS services outlined in **Table 2**.

Table 2. Services provided by the Agency

Services	Details
Development, publication, maintenance and sunsetting of the CAS Framework	The Agency makes these artefacts available on the Digital Health Implementer Hub under the Electronic Prescribing Conformance Assessment Framework¹² Interested parties may register their interest on the website and receive notifications as the documents are updated. The CAS will be subject to ongoing periodical review, to ensure any conformance related issues arising during the CAS' operation are addressed.

¹¹ Australian Digital Health Agency, [Registers](#)

¹² Australian Digital Health Agency, [Electronic Prescribing | Digital Health Implementer Hub](#)

Services	Details
Management of the CAS process	The Agency provides guidance on how EP systems will be tested against the applicable Conformance Profile to satisfy all requirements necessary to declare conformance to the Agency. The Agency also authorises, manages and provides oversight of third-party entities (such as the NPDS) to conduct conformance assessments on behalf of its behalf and may additionally undertake conformance assessments directly.
Support for Electronic Prescribing vendors/implementers	The Agency supports vendors and implementers seeking to declare conformance with the requirements defined in the applicable Conformance Profile. While the Agency may provide guidance on profile applicability and interpretation of requirements within specific contexts, responsibility for confirming conformance rests with the vendor. For support contact help@digitalhealth.gov.au.
Publication and maintenance of the EP Conformance Register	The Agency receives and processes declarations of conformance from software vendors and implementers, ensuring each submission is complete. Once validated, the Agency records the details in the EP Conformance Register, publish the entry on the Registers¹³ on the website, and provides the Conformance ID to Services Australia.

¹³ Australian Digital Health Agency, [Registers](#)

<i>Services</i>	<i>Details</i>
Conformance service quality assurance	The Agency maintains ongoing quality assurance processes to support continued conformance and promote the safety, privacy, efficiency, and effectiveness of the electronic prescribing CAS Framework. The Agency assesses EP incidents and issues reported to the Agency. Where potential or confirmed non-conformance is identified, the Agency supports vendors to remediate issues within agreed timeframes and may remove non-conformant systems from the Register if required. Where incidents highlight gaps in existing conformance requirements, the associated issues and risks are recorded in the electronic prescribing conformance backlog for future mitigation in the next Conformance Profile(s). High risks or issues may require an expedited maintenance release of the Conformance Profile(s).
Support for EP issues	The Agency serves as the central point of contact and escalation for healthcare providers, vendors, and consumers to report electronic prescribing issues, incidents, and suspected non-conformance. For support contact help@digitalhealth.gov.au.

4 Conformance Profile overview

4.1 Conformance Profile Requirements

The EP Conformance Profiles define the functional and non-functional requirements that EP systems must or should meet to perform their roles safely within the ecosystem, acting as controls to mitigate identified risks. These requirements specify how participating systems are expected to behave to support the safe and secure prescribing, dispensing, and use of electronic prescriptions.

Conformant EP systems should meet the following relevant Conformance Profiles corresponding to their role in EP as outlined in **Table 3**.

The examples of system roles in **Table 3** are not an exhaustive or complete list. The system role examples are intended as illustrative examples to assist readers of this document to contextualise which Conformance Profiles may apply in different scenarios.

Table 3. Electronic prescribing Conformance Profile and System role examples

<i>Conformance Profile</i>	<i>System role examples</i>
Consumer-Facing Connecting Systems	• Consumer-facing application • Intermediary
Dispensing System	• Community pharmacy dispensing system • Hospital pharmacy dispensing system
Electronic Medication Chart System	• Hospital electronic medication chart system for inpatient chart based electronic prescribing • Residential aged care electronic medication chart system
General Electronic Prescribing System	• Community general practitioner prescribing system • Community telehealth prescribing system • Hospital electronic medication chart system for outpatient and discharge prescribing
National Prescription Delivery Service and Active Script List Registry	• National Prescription Delivery Service • Active Script List Registry

4.2 Conformance Profile maintenance and sunseting

The Agency will revise the Conformance Profiles periodically as required. Upon release of an updated Profile, software vendors will transition to the latest version in accordance with Agency-defined timeframes. The sunseting of earlier Profile versions will be planned and coordinated by the Agency in consultation with industry to allow sufficient time for conformance testing, assessment and implementation.

There may be identified issues or risks the Agency evaluates as exceeding the Agency's risk appetite in accordance with the [Agency's Clinical Governance Framework](#)¹⁴ and the [Agency's Conformance Framework](#)¹⁵ (for example, issues or risks pertaining to clinical safety or security). To mitigate those issues or risks, the Agency may release an out of cycle Conformance Profile and establish or agree with software vendors on accelerated conformance timeframes.

Sunseting of a Conformance Profile will result in systems versions assessed against that Profile being end dated on the EP Conformance Register.

4.3 Gaps in Conformance Profiles

The Agency is responsible for ensuring that all software operating within the electronic prescribing ecosystem functions in a safe and secure manner.

Any identified gaps (for example through EP investigations or incidents) where existing conformance requirements do not adequately mitigate risks or issues, will be recorded in the EP conformance backlog for consideration into future Profiles.

¹⁴ Australian Digital Health Agency, [Clinical Governance Framework](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.

¹⁵ Australian Digital Health Agency, [Conformance Framework](#), Australian Digital Health Agency website, 2026, accessed 27 August 2026.

5 Conformance assessment approach

This section outlines the Agency's high-level approach to assessing an EP system against the applicable Electronic Prescribing Conformance Profile to determine compliance with the Conformance Profile requirements.

5.1 Understand Electronic Prescribing

To understand EP, refer to the:

- [Electronic Prescribing Conformance Assessment Framework](#)¹⁶ documents, including the Solution Architecture, Conformance Assessment Scheme, and Conformance Profiles.
- [Electronic Prescribing - Conformance Test Specification](#)¹⁷ documents, including the relevant Conformance Profile Test Specifications and Test Data.

5.2 Identification of EP System Role and applicable Conformance Profile

Identify the functions the product will perform within the electronic prescribing ecosystem. Refer to [Section 3.2, Object of Conformance Testing](#) and [Section 4.1, Conformance Profile requirements](#), to identify the relevant system role and applicable Conformance Profile.

5.3 HI Service conformance pre-requisite

Meeting the HI Service Conformance profile requirements is a prerequisite for prescribing and dispensing systems to participate in electronic prescribing.

5.4 NPDS Integration testing pre-requisite

Meeting the NPDS Integration requirements is a prerequisite for prescribing, dispensing and intermediary systems to participate in electronic prescribing. Contact the [NPDS](#)¹⁸ for further information.

5.5 Finalise the conformance process

Complete the conformance process with the NPDS and the Agency, noting that requirements vary depending on the product type. The conformance process conducted by the Agency typically takes approximately 20 business days, in addition to time required for development, testing, self-assessment, and NPDS observed testing.

¹⁶ Australian Digital Health Agency, [Electronic Prescribing | Digital Health Implementer Hub](#)

¹⁷ Australian Digital Health Agency, [Electronic Prescribing – Conformance Test Specifications](#)

¹⁸ National Prescription Delivery Service, [Homepage - eRx Script Exchange](#), National Prescription Delivery Service website, 2026, accessed 1 April 2026.

An overview of the process steps and responsible organisations are provided in [Section 6, *Conformance assessment process*](#).

6 Conformance assessment process

6.1 Observed testing session

Observed testing sessions are conducted by the NPDS; however, there are instances (e.g. an actual or perceived conflict of interest exists) where testing is undertaken by the Agency. Vendors are advised to confirm timeframes for the conformance process.

Upon successful completion of observed testing, the Conformance Test Specifications (CTS) and Electronic Prescribing Observed Test Completion Form will be completed by the NPDS and sent to the Agency.

6.1.1 Conformance test specifications

Conformance Profiles are supported by corresponding [Electronic Prescribing - Conformance Test Specifications](#)¹⁹ which define how compliance with each Profile is demonstrated. These CTS outline the detailed tests and criteria applied during conformance assessment activities.

Conformance Test Specifications include:

1. Test cases:

- a. Each test case translates a conformance requirement, or a component of a conformance requirement, into a concise, insular test with a clear objective and criteria for passing.
- b. Each test case includes:
 - Unique test case number
 - Requirement description
 - Priority (Mandatory, Recommended, Conditional, Optional)
 - Preconditions
 - Test steps
 - Expected results
 - Test data (indicates the type of data required to execute test cases and serves as guidance only for systems participating in EP)

2. Traceability Matrix

- The traceability worksheet links test cases to their corresponding conformance requirements and scenarios.

¹⁹ Australian Digital Health Agency, [Electronic Prescribing – Conformance Test Specifications](#)

- It includes key details such as test case number, requirement reference, and test description to ensure full coverage and traceability.

3. Test Summary Report (TSR)

- The TSR provides a consolidated summary of all test results.
- It captures execution outcomes, including pass/fail status and presents overall completion metrics for the conformance test specifications.

6.1.2 Success criteria

Criteria for successfully claiming conformance to the EP Conformance Profiles include:

1. The system must meet all mandatory and conditionally mandatory requirements by satisfying the specified conditions for the relevant test cases.
2. A 100% pass rate for the test cases corresponding to these requirements
3. A 100% pass rate for all tests for recommended requirements for which a vendor wants to claim conformance.

6.2 Review, verify and validate test evidence

Upon receipt of the CTS and Electronic Prescribing Observed Test Completion Form, the Agency will:

- review the test evidence submitted by the vendor,
- verify that the test results meet the conformance profile requirements, and
- validate that the evidence provides sufficient assurance that the system is able to declare conformance.

6.3 Feedback and supported issue resolution

The Agency will provide feedback to the vendor and, where applicable, support the resolution of identified issues. Where the established conformance requirement success criteria have been met, the vendor will be progressed and requested to complete the Electronic Prescribing Declaration of Conformance Form and Deed Poll.

6.4 Assess declaration of conformance and notify outcome

To declare the conformance of its software system, the vendor must complete and submit the [Electronic Prescribing Declaration of Conformance Form](#)²⁰ to the Agency for assessment. The Agency will then notify the vendor of the outcome.

²⁰ Australian Digital Health Agency, [Electronic Prescribing - Declaration of Conformance v2.0 | Digital Health Implementer Hub](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.

6.4.1 Declaring conformance

Conformance of an EP system will only be declared once the established conformance requirement success criteria have been met.

Vendors must not release any version of software incorporating electronic prescribing capability that is undergoing conformance assessment, and the NPDS must not commence operations involving the connection of electronic prescribing systems to such software, until the Agency has acknowledged receipt of the relevant Declaration of Conformance and the software is listed on the Electronic Prescribing Conformance Register.

6.5 Include software system on conformance register

Once the Agency has assessed the Electronic Prescribing Declaration of Conformance form, the Agency will record the Conformance ID, details and version of the EP system on the EP Conformance Register, published on the Agency's website to conclude the conformance process.

6.6 Production access granted

The Agency will advise the NPDS (and other relevant infrastructure and service operators) and Services Australia of the successful declaration assessment. The NPDS will subsequently action the connection of the conformant system.

6.6.1 Conformance ID assertion

All conformant EP systems must assert a valid Conformance ID when transacting with the NPDS and ASLR. As per the [Electronic Prescriptions Information Technology Requirements 2019²¹](#), this valid Conformance ID must also be included in the metadata of each electronic prescription for every information system involved in generating, sending, receiving, storing, or otherwise processing the prescription.

Dispensing systems must include the Conformance IDs of the prescribing system, NPDS, and dispensing system in all PBS/RPBS claim transactions submitted to Services Australia.

Intermediaries are expected to assert their Conformance ID and the Conformance ID of the requesting consumer-facing application when transacting with the NPDS and ASLR.

²¹ Department of Health, Disability and Ageing, [Electronic Prescriptions Information Technology Requirements Instrument 2019](#)

7 Ongoing validity of conformance

This section describes the process of ongoing conformance assessment for an EP system to the conformance requirements.

7.1 Obligations of re-testing

Re-testing will be triggered by any of the following:

1. **If a version of the EP Conformance Profile is superseded by a new version.**

An EP system that has been declared conformant is encouraged to conform to the new version of the software conformance requirements. This does not remove the requirement to reassess conformance where there has been a material change to EP functionality, as outlined in point 2 below.

In the event an emergency release of the EP Conformance Profiles has been published as outlined in [Section 4.2, Conformance Profile maintenance and sunseting](#) the Agency will establish or agree with software vendors on accelerated conformance timeframes to address and mitigate those issues or risks.

2. **There are material changes to the EP functionality of the system that has previously been declared conformant.** As software systems are continuously updated, changes to source code over time may affect EP functionality previously assessed, potentially invalidating prior conformance testing.

Recognising that some software products update version information frequently for changes that do not affect electronic prescribing functionality, software vendors would usually determine the appropriate level of version granularity and when updates to the Conformance ID are declared. Should the Agency have reasonable grounds to believe that the system's electronic prescribing functionality has been altered, the Agency may request re-assessment.

3. **Software is behaving in a non-conformant manner.** For example, as a result of investigating an incident or system vulnerability.

7.2 Conformance and EP system versioning

A vendor may revise their system to create a new version, including:

1. **A major version**, which may contain significant new functionality compared to the preceding version
2. **A minor version**, which may contain incremental additional functionality compared to the preceding version
3. **A maintenance version**, which may correct one or more defects in a previously issued version.

Regardless of whether a new version is major, minor or a maintenance version, the new version must be retested for conformance if:

- A conforming system is enhanced to support one or more use cases that were not supported by the preceding version of the system. The new version will require conformance testing against every applicable conformance requirement associated with that use case(s).
- A conforming system is enhanced to include sub-sections of use cases that were not tested in the conforming version of the system. The new version will require conformance testing against every applicable conformance requirement associated with the whole use case(s).
- A conforming system is modified so its existing support for software conformance requirements may be impacted. The new version will require conformance testing against every applicable conformance requirement associated with the whole use case(s).

7.3 Validity period

The version of the EP system will remain conformant until one of the below conditions apply:

- The system conformance profile relevant to the declaration of conformance is sunsetted or declared superseded.
- A maximum period of five (5) years from the date of registration for conformance.
- The software is not re-tested in accordance with the obligations detailed in [Section 7.1 Obligations of re-testing](#) of this document.
- The software is subject to investigation or incident, and the software vendor fails to provide requested information in a timeline specified by the Agency or enact an action plan for resolution.
- The software vendor does not comply with the obligations specified in the Electronic Prescribing Declaration of Conformance form and the associated legal agreement
- The legal agreement associated with the conformance declaration expires or is terminated.

The declaration only applies to the version of the EP system and the version of the Electronic Prescribing Conformance Requirements, identified in the Electronic Prescribing Declaration of Conformance form.

7.4 Conformance breaches

The Agency has the ability to remove non-conformant systems from the Conformance Register. As outlined in **Figure 2**, non-conformance issues may be detected when

incidents are reported to the Agency or during conformance monitoring activities conducted by the Agency. If a conformance breach is determined by the Agency, the vendor will be required to undertake re-testing for the breached conformance requirement(s) to remain on the Conformance Register.

7.5 Future state

As part of its responsibility to ensure the safe and secure operation of all systems within the electronic prescribing ecosystem, the Agency will review conformance compliance information from multiple sources to support ongoing software assurance. This includes implementing conformance monitoring activities, such as regular analytics-driven audit testing using system log data and ad-hoc information requests from vendors.

Acronyms and Abbreviations

Acronym/ Abbreviation	Description
ASL	Active Script List
ASLR	Active Script List Registry
CAS	Conformance Assessment Scheme
Conformance ID	Conformance Identifier
CTS	Conformance Test Specifications
EMCS	Electronic Medication Chart System
EP	Electronic Prescribing
HI	Healthcare Identifiers
NASH	National Authentication Service for Health
NPDS	National Prescription Delivery Service
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
SoC	Subject of Care
The Agency	Australian Digital Health Agency
The Department	Department of Health, Disability and Ageing
TSR	Test Summary Report

Glossary

Term	Meaning
Active Script List (ASL)	The ASL is a prescription management system that provides the consumer with a way to view and manage their active electronic prescriptions and barcoded paper prescriptions. The ASL provides only a subset of prescription information, rather than the full details of each prescription.
Active Script List Registry (ASLR)	The ASLR is a national service that provides ASL capability.
Authorised dispenser/pharmacist	A healthcare provider who is permitted under Commonwealth and jurisdictional regulations to dispense medicines and has been granted access to the Electronic Prescribing capability within the dispensing system that enables them to: • create a dispense record and submit it to the NPDS. • update electronic prescriptions (including cancelling/ceasing/disabling/adding annotations) in the NPDS. • update dispense records (including reversal/cancellation) in the NPDS
Authorised prescriber or prescriber	A healthcare provider who is permitted under Commonwealth and jurisdictional regulations to prescribe medicines within their scope of practice and has been granted access to the Electronic Prescribing capability within the prescribing system that enables them to: • create a prescription record and submit it to the NPDS. • update an electronic prescription (including amending/cancelling/ceasing/correcting) in the NPDS
Conformance	A measurement (by testing) of the adherence of an implementation to a specification or standard.
Conformance backlog	A list managed by the Agency of identified gaps, issues and risks where existing conformance requirements do not adequately address observed or potential system behaviour. It is used to prioritise and track items for consideration in future updates to conformance profile requirements.
Conformance Identifier (Conformance ID)	A unique text string of up to 36 printable characters used to uniquely identify the version of the software system which achieved conformance. Conformance IDs are approved by the Agency and remain confidential.
Conformance Register	A publicly available record of software products that have been declared compliant with relevant legislation and conformance requirements, providing visibility of conformant products to healthcare providers and industry stakeholders.

Term	Meaning
Conformant consumer-facing application	A conformant consumer-facing application is an application that has been formally assessed for electronic prescribing conformance requirements, enabling it to be used by consumers to engage with electronic prescriptions. Consumer-facing applications provide users with the ability to manage electronic prescriptions via personal electronic devices. This may be a mobile or web application.
Conformant dispensing system	A conformant dispensing system is a pharmacy dispensing software system that has been formally assessed for EP conformance requirements, enabling it to be used by authorised dispensers/pharmacists to access electronic prescriptions from the NPDS.
Conformant intermediary	A conformant intermediary is a system that has been formally assessed as passing all relevant electronic prescribing conformance requirements and serves as an intermediary for a consumer-facing application, enabling it to access all functionalities provided through/by the NPDS or ASLR.
Conformant prescribing system	A conformant prescribing system is a clinical prescribing software system that has been formally assessed for EP conformance requirements, enabling it to be used by authorised prescribers to generate and transmit electronic prescription activities to the NPDS.
Electronic Prescribing (EP)	The process by which a prescription is electronically generated by an authorised prescriber, authenticated with an electronic signature, securely transmitted to the NPDS for dispensing and supply, downloaded by a dispenser/pharmacist, seamlessly integrated into the dispensing software and, in the case of Australian Government subsidised prescriptions, available to be electronically sent to the Services Australia for claiming purposes under the PBS/RPBS regulations. Notes: 1. This definition does not preclude the use of paper processes to support electronic prescribing activity. 2. Repeat authorisation records uploaded to the NPDS by a dispenser/pharmacist are not electronic repeat authorisations unless the original prescription was generated by an authorised prescriber as an electronic prescription.
Electronic Prescription	An electronic prescription (GEP or CBEP) is generated electronically by an authorised prescriber in a conformant general electronic prescribing system or conformant EMCS, authenticated, securely transmitted to the NPDS for dispensing and supply, integrated into the pharmacy dispensing software and, in the case of PBS/RPBS prescriptions, available to be sent electronically to Services Australia for PBS/RPBS claiming purposes. Notes: The terminology electronic prescription is used in the conformance profile cases where a requirement is applicable to both GEP and CBEP.

Term	Meaning
National Prescription Delivery Service (NPDS)	The NPDS is a national service that enables electronic transfer of prescription information between conformant systems. It provides the mechanism to ensure all prescription information is communicated accurately and securely, supporting safe and efficient supply of medicines
Object of assessment	A digital health system or service, of a digital health system or service, which will be assessed for conformance. E.g. EP system
Software vendor	An organisation that creates an Electronic Prescribing system according to Electronic Prescribing Conformance Profile requirements. A vendor may be an organisation that develops a software product, or a provider of digital health services. The conformance assessment process applies to all of these organisations.
Sunsetting	The planned and managed withdrawal of a Conformance Profile from active use.
Test	The determination of one or more characteristics of an object of conformance assessment according to a documented procedure. Testing is a process applied to software in a test environment.

References

1. Department of Health, Disability and Ageing, [National Health \(Pharmaceutical Benefits\) Regulations 2017](#), Department of Health, Disability and Ageing website, 2026, accessed 30 June 2026.
2. Department of Health, Disability and Ageing, [Electronic Prescriptions Information Technology Requirements Instrument 2019](#), Department of Health, Disability and Ageing website, 2026, accessed 30 June 2026.
3. Australian Digital Health Agency, [Electronic Prescribing | Digital Health Implementer Hub](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.
4. Australian Digital Health Agency, [Electronic Prescribing – Conformance Test Specifications](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.
5. Department of Health, Disability and Ageing, [Legislative and policy framework](#), Department of Health, Disability and Ageing website, 2026, accessed 1 April 2026.
6. Services Australia, [Services Australia](#), Services Australia website, 2026, accessed 1 April 2026.
7. Australian Commission on Safety and Quality in Health Care, [Medication Safety Standards](#), Australian Commission on Safety and Quality in Health Care website, accessed 1 April 2026.
8. Australian Digital Health Agency, [Registers](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.
9. Australian Digital Health Agency, [Clinical Governance Framework](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.
10. Australian Digital Health Agency, [Conformance Framework](#), Australian Digital Health Agency website, 2026, accessed 27 August 2026
11. National Prescription Delivery Service, [Homepage - eRx Script Exchange](#), National Prescription Delivery Service website, 2026, accessed 1 April 2026.
12. Australian Digital Health Agency, [Electronic Prescribing - Declaration of Conformance v2.0 | Digital Health Implementer Hub](#), Australian Digital Health Agency website, 2026, accessed 1 April 2026.