About Software Conformance

Practice Incentives Program (PIP) eHealth Incentive

In order to meet the Practice Incentives Program (PIP) eHealth Incentive requirements, practices must ensure that their software systems are compliant. This is achieved by practices consulting the Digital Health Incentive Product Register to check that their software product and version is on the list of compliant software versions for each relevant PIP eHealth requirement.

Software vendors must declare the conformance of their products and agree to the Terms and Conditions to be included in the Digital Health Incentive Product Register. The requirements to demonstrate software conformance for PIP are provided here.

Note: There is no software conformance requirement for the Data Records and Clinical Coding requirement.

Integrating Healthcare Identifiers into Electronic Practice Records

The intent of this requirement is to make Healthcare Identifiers available for electronic messaging and for use in the My Health Record system.

Clinical software systems must demonstrate the capability of direct access to the Healthcare Identifiers (HI) Service by completing HI conformance testing, as documented in the HI Conformance Assessment Scheme. The conformance tests are performed by independent National Association of Testing Authorities (NATA) accredited testing laboratories to assure the safe use of Healthcare Identifiers by clinical software systems. Conformance assessment must be performed by a test laboratory accredited by NATA under its classification 22.40.02 in the NATA Information and Communications Technology Testing, Classes of Test.

The Software Conformance Requirements for HI provide detail of the clinical software system behaviour and refers to relevant Business Use Cases (Business Use Cases and the Software Conformance Requirements).

To be eligible for the PIP eHealth incentive, a clinical software system must have the following minimum scope of conformance.

Healthcare Provider Identifier – Organisation (HPI-O)

The clinical software system must be capable of recording the HPI-O for the practice.

If the clinical software system is capable of registering and maintaining the HPI-O online, then it must have successfully completed conformance testing for the following use cases:

- Use Case 080: Maintain HPI-O details; and
- Use Case 150: Register network HPI-O.

Healthcare Provider Identifier – Individual (HPI-I)

The clinical software system must be capable of recording the HPI-I for each general practitioner within a practice.

There is no software conformance requirement for this recording function.

Individual Healthcare Identifier (IHI)

For a clinical software system to be conformant for the PIP eHealth Incentive in the way it processes IHI(s) and be included in the Register, it must have successfully completed conformance testing for the following list of use cases:

- Use Case 010: Register patient (for verified IHI only); and
- Use Case 015: Update patient health record or Use Case 025: Bulk update of IHI details.

Healthcare Identifier (HI) Service

In order to achieve the above requirements for HPI-O, HPI-I and IHI, a clinical information system must also implement the web services for the HI Service operated by the Department of Human Services (DHS). The HI Service Licensed Material contains information for developers such as the HI Service System Interface Specifications, HI Service Developers Guide, Web Services Description Language definitions and XML Schema definitions. The Licensed Material may be obtained when developers accept the terms and conditions of the Licence Agreement for Healthcare Identifiers Service software developers.

DHS manages the NOC testing process. The NOC tests that a software system can connect to the HI Service. DHS does not charge developers to test for a NOC.

NOC testing is performed independently to the HI conformance tests. The HI conformance tests are performed to assure the safe use of healthcare identifiers by a health software system and the NOC tests are performed to determine that software can connect to the HI Service. A HI Production Access Letter will be issued when the software has successfully completed both conformance testing and the DHS's NOC testing.

Further information in regards to the Licensed Material and NOC testing process may be obtained from the Healthcare Identifiers Service for health professionals section on the DHS website.

Secure Electronic Communications

For clinical software system to be conformant for PIP in the way it uses healthcare identifiers in secure electronic communications and be included in the Register, it is recommended to have successfully completed conformance testing for the following list of use cases:

- Either Use Case 241: Search for HPI-Os in HI Service HPD, or Use Case 305: Validate HPI-O.

The software system is recommended to have performed conformance testing for the following use cases:

- Use Case 325: Receive patient health information electronically (for IHIs); and
- Use Case 330: Send patient health information electronically (for IHIs).

Other Requirements

If the clinical software system performs linking of HPI-Is and HPI-Os online, or publishing HPI-Is and/or HPI-Os to the HPD online, then it is recommended to conform with the following use cases:

- Use Case 135: Publish HPI-O to HPD;
- Use Case 175: Link HPI-I to HPI-O;
- Use Case 215: Maintain HPI-I Details; and
- Use Case 225: Publish HPI-I in the HPD.

When you have successfully completed the conformance requirements for your software product to access the HI Service you can complete the Declaration of Conformity Form and request to have your software recorded in the Digital Health Incentive Product Register using the Registration page.

Secure Messaging Capability

The practice requirement is to "have a standards-compliant secure messaging capability." This is a pre-requisite to enable the health messaging software system to interoperate with other products which conform to the same specification.

While it is possible that a health messaging software system used in a practice may have a "native" capability to send and receive secure

messages, in most cases the sending and receiving of secure messages is likely to be via a messaging service provider.

The practice requirement allows for an SMD messaging capability to be delivered by either means. Whichever approach is used, the SMD messaging capability must conform to the Standards Australia technical specifications for SMD ATS 5822-2010.

Listings on the Digital Health Incentive Product Register for secure message delivery may be sought by messaging service providers, and by those vendors of health messaging software systems which have a "native" SMD messaging capability.

Health messaging software systems used in practices need not appear on the Digital Health Incentive Product Register for secure message delivery – only in those cases where such a system has a native SMD capability. It is intended that a practice will establish its SMD compliance by checking that either its messaging service provider is listed on the Register, or that its SMD-capable health messaging software system is listed on the Register.

Conformance is demonstrated by independent testing by a National Association of Testing Authorities (NATA)-accredited testing facility. Conformance assessment of SMD software products must be performed by a test laboratory accredited by NATA under its classification 22.40.01 in the NATA Information and Communications Technology Testing, Classes of Test.

A test report as evidence of such testing should be submitted with an application for listing.

Refer to the NEHTA website for more information on software conformance for SMD.

Software vendors who wish to claim software conformance to the requirements for SMD must complete the Implementation Conformance Statement (ICS) for SMD to indicate which requirements are satisfied by their SMD implementation before submitting their software to an accredited test laboratory for formal testing.

The minimum requirements for PIP-compliance are:

- Full Sender function or Sender function with a Sender Intermediary; and
- Full Receiver function or Receiver function with a Receiver Intermediary.

The functions are defined as follows:

- A full Sender function is defined as a Sender with a TRD interface;
- A full Receiver function is defined as a Receiver with a SMD interface;
- A Sender function with a Sender Intermediary means that the Sender does not have a TRD interface and uses the services of a Sender Intermediary to provide this capability; and
- A Receiver function with a Receiver Intermediary means that the Receiver does not have a SMD interface and uses the services of a Receiver Intermediary to provide this capability.

When you have successfully completed the conformance requirements for your software product to participate you can complete the Declaration of Conformity (SMD) Form and request to be recorded in the Digital Health Incentive Product Register using the Registration page.

In addition to the above conformance requirements, PIP requires practices to ensure that their SMD systems are properly deployed for operation, as described in the *Commissioning Requirements for Secure Message Delivery*.

Data Records and Clinical Coding

There is no software conformance requirement for Data Records and Clinical Coding.

Electronic Transfer of Prescriptions

The practice software system must be able to send an electronic prescription to a Prescription Exchange Service (PES) operator for later retrieval by a dispenser at the time of dispensing.

There are no current conformance software conformance requirements for practice systems for the Electronic Transfer of Prescriptions (ETP).

If your software product is able to send an electronic prescription to a PES operator you can contact help@nehta.gov.au for a Declaration of Conformity form and request to be recorded in the Digital Health Incentive Product Register using the Registration page.

My Health Record system

The practice requirement is to use compliant software for accessing the My Health Record system, and creating and posting shared health summaries and event summaries; Apply to participate in the My Health Record system upon obtaining a HPI–O; and upload a shared health summary for a minimum of 0.5% of the practice's standardised whole patient equivalent (SWPE) count of patients per PIP payment quarter.

Conformance assessment provides assurance that a clinical software system adheres to digital health specifications as defined in the PCEHR CIS conformance assessment scheme. It gives users of conforming implementations confidence that an implementation will behave as expected, perform functions in a known manner, has interfaces or formats that adhere to agreed specifications, and is likely to interoperate with other conforming implementations.

Conformance testing for software vendors is performed according to the approved self-assessment process outlined on the My Health Record Developer website. It is a process which enables a developer to assess their own software system, using the test documentation and tools provided by NEHTA.

The scope of conformance for the PIP eHealth Incentive includes the functions for Shared Health Summaries (and Event Summaries) as described in the Clinical Information Systems Business Use Cases.

To be eligible for the PIP eHealth incentive, a software system must have the following minimum scope of conformance.

As specified in the CIS conformance assessment scheme, the software must meet the Conformance Requirements of both a CIS Producer (upload a clinical document) and a CIS Consumer (download a clinical document) for Shared Health Summary (and later, for Event Summary).

The relevant use cases, described in PCEHR Business Use Cases, are:

- UC.CIS.001
- UC.CIS.002
- UC.CIS.201
- UC.CIS.202 (not required for Shared Health Summaries)
- UC.CIS.203
- UC.CIS.204

Refer to the My Health Record Developer website for more information on the conformance requirements of software systems connecting to the My Health Record system.

When you have successfully completed the conformance requirements for your software product to participate you can complete the PCEHR Declaration of Conformity Form (which can be obtained by emailing MyHealthRecord.Operations@health.gov.au) and request to be recorded in the Digital Health Incentive Product Register using the Registration page.