

## Compliance Roadmap for the Healthcare Identifiers Service

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### Introduction

The objective of this paper is to inform the health IT industry about the conformity assessment process being developed to support the implementation and adoption of the national Healthcare Identifiers (HI) Service. This process reflects NEHTA's general approach to conformity assessment underpinned by a [Consensus Statement](#) endorsed by software industry representatives in November 2009.

### Assessment approach

The NEHTA conformity assessment requirements apply to the use of the HI Service by "client" applications – the software systems that use the national service operated by Medicare Australia. These requirements are separate and additional to the HI Service software tests required to fulfil Medicare Australia's Notice of Integration (NOI) process.

The NEHTA conformity assessment process has two parts.

- 1. HI Service client behavioural compliance:** NEHTA's HI Service client behavioural compliance ensures that HI client software demonstrates proper behaviour in its use of healthcare identifiers. Proper behaviour refers to the manner in which applications acquire, use, and manage healthcare identifier information as this can affect clinical safety, information security and privacy risks and improper behaviour may undermine the integrity and benefits of the HI Service.

To address risks of improper use of identifiers, two different checklists are being developed – one covering software product development and one covering system operation and deployment. Compliance with these requirements is to be determined by independent inspection. The two checklists are:

- 1) A developer checklist which provides guidance for the design and construction of software products.
- 2) An operational compliance checklist which applies to deployed software systems, to ensure such systems acquire, use and administer Australian Healthcare Identifiers in a way consistent with legislation, regulations and NEHTA/Medicare Australia technical specifications.

Where deployments of a product are uniform (eg a general practice management system that is consistently deployed in many different locations) then the operational compliance checklist would apply to the developer. Where deployments are customised, or differ in their use of identifiers, then the operational compliance checklist may be applied as part of the specific or custom deployment.

- 2. HI Service B2B web services interface conformance:** In addition to the HI client behavioural compliance assessment above, NEHTA has developed software conformance test specifications for testing the B2B web service interface between a software system and the HI Service. These tests extend the routine tests performed by Medicare Australia in its software certification process.

## Medicare Australia requirements

Medicare Australia's testing requirements for systems accessing the HI Service are described in their document "Healthcare Identifiers (HI) Service Developers Guide" and information about their process should be obtained from Medicare Australia.

Developers register with Medicare Australia in order to receive the guide and to gain access to the integration test platform operated by Medicare Australia's Online Technical Support (OTS) branch. Medicare Australia's product certification testing checks that software products using the HI Service are able to access the service, that B2B messages (transmission headers and payload) are an acceptable format, and that the software does not pose any risk to Medicare Australia's production environment. It is mandatory that software products pass these product certification tests, and be issued with a Medicare Australia Notice of Integration (NOI), before they are granted access to the national HI Service.

## Target end-to-end process

In summary, the key assessment steps for developers are:

1. Obtain both HI client developer and operational compliance checklists and the HI B2B interface conformance test specifications from NEHTA to guide product design and construction.
2. Seek third-party laboratory assessment of the final software product. This independent testing reflects the importance of conformity as a way of managing clinical safety, information security and privacy risks. Where common deployments of the product are made across many sites, the assessment should use both the developer and operational compliance checklists. Where the product is being used on a custom deployment, only the developer checklist should be used.
3. Software products successfully passing the independent test process have the option of being included on an Australian Register of Conformity published by NEHTA.
4. Separately, HI client software must also pass Medicare Australia's testing process to receive a Notice of Integration (NOI) and be granted access to the HI Service.

The HI client assessment process is expected to be operational by March 2011. Following a period of stakeholder consultation, final support materials are due for release in December 2010 and the conformity assessment scheme will continue to evolve over time. NEHTA is working closely with industry stakeholders to develop and agree the requirements, risk assessment and compliance scheme for HI client software systems.

## Phase-in and consultation

The HI client assessment process is expected to be implemented in the first half of 2011.

In support of this, the assessment scheme and its associated materials will be released by December 2010. These materials include:

1. HI client behaviour developer checklist.
2. HI client behaviour operational compliance checklist.
3. HI client B2B web services interface conformance test specification.

In the interim, NEHTA will release a draft HI client behaviour developer checklist and its HI Service conformance test specification to provide early guidance to developers.

The conformity assessment scheme will continue to evolve over time. NEHTA is working closely with industry stakeholders to develop and agree the requirements, risk assessment and compliance scheme for HI client software systems.

Tests will apply to new software products and versions and will not be retrospectively applied. There will be ample advance notice provided before conformance requirements are released.

## Industry testing and tools

NEHTA has developed behavioural compliance criteria and conformance test specifications to ensure that developers and independent testing laboratories use a common baseline and approach when assessing software products. These assessment tools are proposed to be used by the National Association of Testing Authorities (NATA) for any NATA-accredited laboratory that wishes to offer HI testing services. The laboratory accreditation scheme is expected to be in place by December 2010 with testing services, and inspection capabilities, being commercially available during 2011.

Tests will apply to new software products and versions and will not be retrospectively applied and there will be ample advance notice provided before any additional conformance requirements are released. The cost of software testing will be determined by market forces however NEHTA is keen to ensure compliance overheads are as low as possible.

In coming years, if an e-health software certification scheme is agreed and introduced, NEHTA will seek the support of JAS-ANZ, the government appointed accreditation body for Australia and New Zealand, to design an appropriate certification scheme to be implemented by independent certification bodies.

## Summary

*What do vendors need to do?*

Vendors should obtain from NEHTA the draft HI client developer checklist and the B2B conformance test specification in order to inform their product development and prepare them for third-party testing.

Developers should register with Medicare Australia in order to complete their software certification process and obtain a Notice

of Integration.

*What will it cost?*

There are no direct costs for registration or product certification testing with Medicare Australia.

The cost of independent HI behavioural testing and software conformance testing will be determined by the market.

*What controls will there be over the amount of testing required?*

The software industry is being consulted about assessment and testing requirements for the conformity assessment process as part of an ongoing engagement program around HI Service implementation.

**For more information:**

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