

## NEHTA responses to Electronic Transfer of Prescriptions (ETP) PIA recommendations

NEHTA has developed specifications for the Electronic Transfer of Prescriptions (ETP) through broader stakeholder consultation including clinical peak bodies, state, territory and commonwealth governments and agencies. Specific stakeholder involvement can be found in the Acknowledgement section of the ETP Specification Version 1.1 that can be found at:

<http://www.nehta.gov.au/e-communications-in-practice/emedication-management>

The Privacy Impact Assessments (PIA) undertaken in the development of the specification provide independent assurance of alignment with privacy principles, with the 2010 PIA including specific consultation with Consumer groups.

This document outlines the actions NEHTA took to respond to recommendations in the PIAs.

### Electronic Transfer of Prescription Preliminary Privacy Impact Assessment 2009 completed by Better Life ICT.

#### Recommendations and responses

<p><b>Recommendation 1:</b> Standardise the terminology used in the ETP project associated with the various sub-systems and encryption keys.</p>	<p>NEHTA Response: <b>Implemented</b></p> <p>The terminology has been standardised in documents issued for comment in November 2009.</p>
<p><b>Recommendation 2:</b> Provide the Prescriber with the discretion of choosing what information will be entered in the mandatory fields on the PES to accommodate situations when an individual has special circumstances.</p>	<p>NEHTA Response: <b>Implemented</b></p> <p>The revised Structured Document Template only requires Name and Address as mandatory personal information as required by National Health (Pharmaceutical Benefits) Regulations 1960 (Cth) and the various drug and poisons control regulations in each state and territory. The ETP specifications do not in any way restrict a Prescriber's current ability to exercise discretion in the completion of the name or address.</p> <p>National Healthcare Identifiers were made mandatory in Release 1.1. The PIA on Release 1.1 did not make any recommendations on this matter.</p> <p>Doctors may still provide paper prescriptions where a patient requests it.</p>
<p><b>Recommendation 3:</b> Ensure that individuals can readily access the applicable privacy policies associated with eMM and wherever possible provide these policies in other commonly used languages, in line with Government practice.</p>	<p>NEHTA Response <b>No Action</b></p> <p>Privacy policies associated with prescription of medications (and other aspects of the handling of personal information) are the responsibility of prescribing and dispensing organisations. The ETP specifications are designed to support</p>

	<p>current clinical practice. Prescribing and dispensing organisations should review their existing privacy policies when implementing ETP to ensure that they are meeting their obligations under privacy laws.</p>
<p><b>Recommendation 4:</b> The definition and application of a confidentiality indicator should be considered as a high priority. As an interim measure the confidentiality indicator should be specified as 'reserved' and clearly stated that this is reserved for future application and cannot be assigned any value.</p>	<p>NEHTA Response <b>Implemented</b></p> <p>This field is part of the HL7 Clinical Document Architecture international standard. In the CDA Implementation Guide, NEHTA has specified that this field must contain "Not Application". A test for the non-use of this field will be included in the CCA scheme that is under development.</p>
<p><b>Recommendation 5:</b> Resolve the issue of consent for Dispense Notification by referring to the appropriate reference groups for further consideration.</p>	<p>NEHTA Response <b>Implemented</b></p> <p>The capability to provide Dispense Notifications has been removed from the scope.</p>
<p><b>Recommendation 6:</b> Develop methods and policies that minimise the risk associated with the creation of lists of previously assigned PDP.tokens.</p>	<p>NEHTA Response <b>NEHTA agrees</b></p> <p>NEHTA will work with clinical peak bodies to include information on Document Access Key (PDP.token) management in practice management and pharmacy management guidelines.</p>
<p><b>Recommendation 7:</b> Provide suitable access mechanisms that permit individuals to exercise their right to access any personal information stored electronically and to request corrections to errors if necessary.</p>	<p>NEHTA Response. <b>NEHTA agrees</b></p> <p>Individuals can request access to stored information through their prescriber or dispenser. Individuals can request correction (via cancellation and replacement of the prescription) through their prescriber. The PES disallows the retrieval of cancelled prescriptions.</p>
<p><b>Recommendation 8:</b> Include specifications of the back-up and audit functions of the PES to ensure that personal data is only stored in encrypted form.</p>	<p>NEHTA Response <b>NEHTA refers this to government</b></p> <p>NEHTA does not have the authority to determine the operating environment of commercial organizations.</p>
<p><b>Recommendation 9:</b> Ensure robust mechanisms are employed for generating PDP.tokens (and the PDP.id / PDP.key) in a secure and dependable manner.</p>	<p>NEHTA Response <b>NEHTA agrees</b></p> <p>The document access generation mechanism for the Document Access Key has been independently reviewed and deemed to be highly robust number generation.</p>

<p><b>Consideration:</b> A reference is provided on the prescription to where an individual can find the full set of privacy terms and conditions and which ones would apply to private and PBS claimed prescriptions respectively.</p>	<p>NEHTA Response.  <b>NEHTA agrees in principle</b></p> <p>Prescriptions and dispense records are managed and stored by prescribers and dispensers and therefore management of that information falls under the responsibility of the healthcare provider.          NEHTA will refer to Medicare Australia the need for the current PBS privacy statement on a paper prescription to be retained in an alternate form for ETP prescriptions.</p>
<p><b>Consideration:</b> Plain text record header can be retained but the encrypted payload should be deleted from the system whenever a prescription is cancelled.</p>	<p>NEHTA Response  <b>NEHTA disagrees</b></p> <p>Cancelled prescriptions will be retained by Prescriptions Exchanges for the period required by records keeping law, after which time they may be deleted.</p>
<p><b>Consideration:</b> The encrypted payload in the PES is deleted when reasonably practicable past the expiry date.</p>	<p>NEHTA response  <b>NEHTA agrees</b></p> <p>NEHTA will recommend that prescriptions and dispensed records are retained in line with record keeping laws through any future prescription exchange governance arrangements</p>

**Electronic Transfer of Prescription Privacy Impact Assessment 2010 completed by Information Integrity Solutions.**

Recommendations and responses

<p><b>Recommendation 1: Business as usual – Transparency and e-Prescription notifications</b>          IIS recommends that NEHTA include in its specifications for ETP that individuals should be entitled to receive an e-Prescription notification that includes all the personal information and clinical content on the e-Prescription. The specifications should require prescribers to offer the option of a paper notification. The notification should include information about where an individual can get more information about ETP.</p>	<p>NEHTA Response:  <b>NEHTA agrees in principle</b></p> <p>NEHTA has not specified the content of the prescription notification in this release. As part of our requirements development process, this item will be subject to consultation with government clinical and consumer stakeholders in 2011. Outcomes of the consultation process will be incorporated into our Conformance, Compliance and Accreditation scheme published in 2011.</p>
<p><b>Recommendation 2: Business as usual – Community awareness and education about ETP</b>          IIS recommends that NEHTA ensures that before and after ETP comes into operation there is an extensive community awareness and education campaign about ETP and how it works. It should include online tools, as well as a brochure that can be handed to the individual at the time an e-Prescription is issued and when an e-Prescription is dispensed.</p>	<p>NEHTA Response:  <b>NEHTA refers this to government</b></p> <p>This initiative falls outside the scope of NEHTA’s work program. NEHTA will recommend that the government undertake extensive community awareness and education campaigns about ETP and how it works.</p> <p>NEHTA acknowledges existing operations of electronic prescribing and dispensing and notes that there is a clear role for professional organisations, governments and NEHTA in ensuring appropriate information is available on the ETP.</p>
<p><b>Recommendation 3: Technology – Gender in an e-Prescription</b>          IIS recommends that there should not be a specific field for recording gender in an e-Prescription.</p>	<p>NEHTA Response  <b>Further consultation required</b></p> <p>NEHTA notes that IIS was unable to ascertain a reason for the inclusion of gender which led to this recommendation. However, members of NEHTA’s Medications Management Reference Group and broader consultation with industry have expressed the view that inclusion of gender can have significant clinical safety benefits particularly in circumstances where the consumer is not visible or in communication with the pharmacist, which the ETP process supports. The exclusion of gender in this scenario could open opportunities for error, noting that the data item is optional.</p>

	<p>NEHTA also acknowledges that at the point of prescribing, gender is an important factor in safe and appropriate prescribing and notes Pharmaceutical Benefits Scheme recommendations on, for example, cholesterol-lowering drug therapy, where the patient has urinary albumin to creatinine ratio of &gt; 2.5 for males &gt; 3.5 for females).</p> <p>NEHTA will conduct further consultation with clinical and consumer stakeholders to confirm the clinical and safety benefits.</p>
<p><b>Recommendation 4: Technology – Date of Birth in an e-Prescription</b>          IIS recommends that an e-Prescription retains a field for recording age (years and /or months) but that specifications require that the field only be used when the individual is under the age of 12.</p>	<p>NEHTA Response  <b>NEHTA agrees in principle</b></p> <p>NEHTA acknowledges that at the point of prescribing, age is an important factor in safe and appropriate prescribing and notes Pharmaceutical Benefits Scheme recommendations on, for example, cholesterol-lowering drug therapy, where the patient has diabetes mellitus and aged over 60 years.</p> <p>There is also a legal requirement to record Date of Birth under state and territory legislation governing controlled substances.</p> <p>NEHTA will confirm with clinical stakeholders that this use case (i.e. recording the age of individuals under the age of 12) is the only clinical use case and there are not other circumstances when recording age may be relevant.</p>
<p><b>Recommendation 5: Technology – Configuration of ETP software</b>          IIS recommends that ETP specifications require that ETP software that pre-populates e-Prescriptions only includes information that is necessary for the particular prescription being issued.</p>	<p>NEHTA Response  <b>NEHTA agrees in principle</b></p> <p>NEHTA has specified the information required for prescribing and dispensing based on broad stakeholder consultation. Prescribers will continue to use clinical judgment in communicating only the necessary information.</p>

<p><b>Recommendation 6: Business as usual – Transparency relating to disclosure of dispensing records</b></p> <p>IIS recommends that should the notification of dispense on cancellation of prescription proceed protocols developed for participants in the ETP include specifications about how individuals are to be informed that dispensing information could be given to the prescriber and of the circumstances in which this could happen. It should be included in the education and awareness campaign conducted on the implementation of the ETP specifications.</p>	<p>NEHTA Response <b>NEHTA agrees</b></p> <p>NEHTA has removed this functionality from the specification. We note the alternative that was provided in the PIA and we have accepted this. NEHTA will not be implementing this recommendation as the risk has been removed.</p>
<p><b>Recommendation 7: Business as usual – Policies and procedures for consent to notify prescription</b></p> <p>IIS recommends that NEHTA ensure that there are appropriate policies and procedures in place to ensure that a prescriber does not send, and an aged care facility or private hospital does not receive, prescription notifications unless the individual or their authorised representative has given the appropriate form of consent.</p>	<p>NEHTA Response. <b>NEHTA agrees</b></p> <p>Policies for the proper and safe use of ETP are the subject of planned consultation with clinical, consumer and aged care sector stakeholders in 2011 and will consider any impact this has on the way care is managed.</p>
<p><b>Recommendation 8: Business as usual and technology security and notification agents</b></p> <p>IIS recommends that the same security mechanisms that will apply to prescribers, PES, and dispensers should also apply to Notification Agents.</p>	<p>NEHTA Response <b>NEHTA agrees</b></p> <p>Policies for the proper and safe use of ETP are the subject of planned consultation with clinical and consumer stakeholders in 2011. Outcomes of the consultation process will be incorporated into our CCA scheme published in 2011. NEHTA also recognizes that this issue relates to ETP governance and will refer this issue to the government.</p>
<p><b>Recommendation 9: Business as usual – Transborder data flows</b></p> <p>IIS recommends that a PES provider should not be approved as meeting the NEHTA specifications if it proposes to transmit or store e-Prescription data outside Australia unless there has been a Privacy Impact Assessment including public consultation which establishes that</p>	<p>NEHTA Response <b>NEHTA agrees that transborder data flows must comply with current legal obligations and refers governance requirements to Government</b></p> <p>NEHTA acknowledges existing legal obligations which require organisations sending personal information overseas to meet certain requirements. These requirements are aimed at</p>

<p>the e-Prescription information can be protected to the level it would have if it remained in Australia.</p>	<p>ensuring that outbound information is handled appropriately. In addition to this, Pharmacists are eligible for an electronic prescribing payment under the Fifth Community Pharmacy Agreement, where a prescription exchange that has been subjected to an independent privacy impact assessment to ensure that prescribers and Approved Suppliers meet their obligations under the Privacy Act 1988 (Cth). NEHTA specifications do not impose governance requirements on PES providers; therefore NEHTA refers this recommendation to Government as part of Recommendation 10.</p>
<p><b>Recommendation 10:</b> IIS recommends that NEHTA advocates the need for there to be put in place an appropriate governance mechanism to ensure that there is:</p> <ul style="list-style-type: none"> <li>• a mechanism for ongoing oversight of the operation of ETP as a whole;</li> <li>• a mechanism for developing a consistent and coordinated approach to: <ul style="list-style-type: none"> <li>○ policy relating to the ETP;</li> <li>○ information and transparency about how the ETP operates, the role of each participant and the information flows between the participants;</li> <li>○ implementing audit and accountability mechanisms to ensure that all participants comply with the applicable privacy and security requirements and obligations – this should include independent audits and random inspections carried out on processes used by PES operators and</li> </ul> </li> </ul>	<p>NEHTA Response <b>NEHTA refers this to government</b></p> <p>NEHTA is aware that arrangements for long term eHealth governance were referred to the Chair of the National eHealth and Information Principal Committee (NEHIPC) for advice to Australian Health Ministers before the end of 2011.</p> <p>NEHTA does not have the authority to establish governance over the ETP environment and will refer this recommendation to the government for on-going management as part of broader governance arrangements being considered by NEHIPC.</p>

<p>dispensers;</p> <ul style="list-style-type: none"> <li>○ providing access to information held by the participants where necessary or an emergency;</li> <li>○ managing failure and complaints;</li> <li>○ developing fair terms and conditions, if any, imposed on individuals in relation to the ETP;</li> <li>○ monitoring and managing function creep;</li> <li>● Public reporting on the operation of ETP in relation to each of these matters</li> </ul>	
<p><b>Recommendation 11: Undispensed e-Prescriptions</b>  IIS recommends that NEHTA does not provide for the capability to include in records associated with an e-Prescription the information that a dispense was unsuccessful or the reasons why.</p>	<p>NEHTA response  <b>NEHTA agrees</b></p> <p>The functionality has been removed from the specifications.</p>