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Dr Ian Holland
Secretary
Community Affairs Committee
Parliament House
CANBERRA ACT 2600

Dear Dr Holland

Further to your invitation dated 31 January 2012, and to assist the Committee with its deliberation around the Inquiry into the Personally Controlled Electronic Health Record Bill 2011, please find attached:

1. NEHTA's combined formal response to the MSIA's written submission, provided to the Inquiry on 24 January 2012; and to the MSIA testimony, provided to the Inquiry at its public hearing on Monday 6 February; and
2. NEHTA's formal response to the MSIA *The National Healthcare Identifier Service Current State and Issues* whitepaper, published in November 2011.

I would also like to assure the Committee that NEHTA is working to provide copies of clinical safety documents as requested at the public hearing. These documents will be provided to the Committee as soon as possible.

NEHTA welcomes the opportunity to assist the Committee with any further information it may require in the course of its duties relating the inquiry.

Yours sincerely

Peter Fleming
Chief Executive

NATIONAL E-HEALTH TRANSITION AUTHORITY

RESPONSE TO

THE MEDICAL SOFTWARE INDUSTRY ASSOCIATION (INC) WHITEPAPER

FROM THE MSIA CEO FORUM 18-19 October 2011

The comments below are NEHTA and DHS responses to the claims made in the MSIA white paper *The National Healthcare Identifier Service current state and issues November 2011.*

NOTE: *NEHTA and DHS responses are in italics*. Some DHS feedback has been incorporated into NeHTA comments.

The responses have been presented in a format where they follow the comments or claims to which they respond.

MSIA Issues 1:

The HI service as currently implemented provides no benefit for identifying patients over that provided by a Medicare Number or DVA number for the vast majority of patients.

NEHTA Response 1:

The Medicare number cannot be relied upon as a unique identifier for healthcare and cannot be a substitute for the IHI. The Medicare number is not fit for purpose due to a number of factors. For instance, an individual may have one or more Medicare Card's and associated Medicare numbers. For example, a child with separated parents may be listed on both their mother's and father's Medicare cards.

MSIA Issue 2:

Some concerns over issues for patient safety remain unaddressed.

NEHTA Response 2:

NEHTA, DHS Medicare and the stakeholders have a comprehensive risk

management strategy to safety. This includes the assurance processes and controls from the NEHTA clinical safety unit, NEHTA and DHS design and delivery programme governance mechanisms, and the stakeholder driven Conformance, Compliance and Accreditation (CCA) process. We do not agree there are issues unaddressed. Risks that are identified and verified are appropriately managed through these governance forums.

MSIA Issue 3:
Software vendors connecting to the live HI service assume all liability for outcomes and potentially expose their employees and companies to serious sanctions, including jail terms.

NEHTA Response 3:
NEHTA is requesting further guidance from DOHA on how liabilities and penalties apply to contracted service provider and "shrinkwrap" software providers in context with the HI Act. Of note, there are no specific penalties within the HI Act. for the software vendor community.

MSIA Issue 4:
It is not possible to electronically discover or verify the vast majority of HPI-Is or HPI-Os (those that have not opted into the Medicare Provider Directory) and there is little experience in their use. It will be necessary to enter HPI-Is and HPI-Os manually into software systems and any accidental misallocation of an HPI-I to the wrong provider or an HPI-O to the wrong organisation, will be unable to be detected. This invalid data will then be able to disseminate via messaging, throughout the eHealth system as none of the receiving systems will be able to perform a validity check.

NEHTA Response 4:
As part of the design and development of the HI legislation and HI Service the clinical community was extensively consulted on privacy issues pertaining to the

disclosure of healthcare provider identifiers. (HPI-I and HPI-O)
Based on this consultation the privacy settings were for an "opt-in" model for disclosure of the HPI-I and HPI-O to the healthcare community.
Since enablement of the HI legislation and go-live of the HI Service, stakeholder feedback has been to revisit this and review if it is possible to discovery and verify the healthcare provider identifiers. NEHTA, DHS, and DOHA are currently investing options for enabling this request but must consider both legal and privacy review before any changes are made.

MSIA Issue 5:
There are very few HPI-Os and little or no experience in their use.

NEHTA Response 5:
There are over 624 HPI-O's registered with the HI Service and a number of lessons have been learned from the early uptake to date. These lessons have been incorporated into service delivery improvements for providers and the additional development of user guides to assist the community in the effective use of the identifiers.

MSIA Issue 6:
The inability to verify the relationship between an HPI-I and HPI-O (other than for an organisation's administrators) has serious implications for utility and safety of proposed specifications for electronic transfer of prescriptions (ETP) as well as a number of other electronic documents.

NEHTA Response 6:

The MSIA is suggesting there needs to be an ability to verify the relationship between the HPI-I and the HPI-O outside of the verification undertaken by an organisation's maintenance officer. This is the equivalent of needing to verify a BSB number for a banking transaction prior to the transaction.

There is currently no policy or design that leverages the linking capability in the HI Service as part of the ETP workflow or any other peer to peer electronic documents.

MSIA Issue 7:

Medicare is unwilling to reveal figures on HI service usage, HPI-O availability or Provider Directory opt-in rates other than once a year in its annual report published for the first time recently.

NEHTA Response 7:
DHS Medicare regularly discloses the current figures of HI Service usage at the ICT Committee (which includes representatives from the AIIA and MSIA).

Identifier Type	Count - Dec 2011
Individual Healthcare Identifiers (IHI)	24,301,436
Healthcare Provider Identifier - Individual (HPI-I)	467,483
Healthcare Provider Identifier - Organisation (HPI-O)	624

MSIA Issue 8:
NeHTA continues to not disclose relevant HI Service patient safety risk assessments and will not reveal quality control and patient safety oversight of the Wave 1 IHI roll-out.

NEHTA Response 8:
NEHTA has not released any reports to date, so as to avoid "point in time" data being taken out of context or conflated with a later date.

NEHTA has fully disclosed the testing and assessment methodology for the HI Service, the results of testing, and a summary of safety assessments, in a personal briefing to the MSIA leadership during a regular engagement update in January 2011.

DHS also hosted MSIA members to visit and "walkthrough" the DHS physical IT environments to demonstrate how the testing assurance regime is conducted.

The MSIA CEO also has a paper detailing a summary of work and the methodology used within NeHTA. This system of assessing Clinical safety and the processes before the assessment, in plan and build phase of the products and indeed at the point of sign off as ready for the market are benchmarked.

A recent review was conducted by BT, one by the University of NSW and another by Ernst and Young. Subsequent benchmarking is also underway by the Australian Commission of Quality and Safety in Health.

On-going validation is planned with Clinical groups to show them the methodology and a view of the Clinical Safety framework. This is not an easy process to learn from volumes of technical notes which read out of context and in isolation would be time consuming, confusing, unhelpful and indeed subject to erroneous interpretation.

NEHTA is currently in process of preparing a current clinical safety report for release on the HI Service.
Discussions are being held with DHS, after which NEHTA will complete an update to the HI Service report to enable its immediate release.

MSIA Issue 9:
NeHTA have assured MSIA that all Wave 1 contracts include appropriate liability waivers for software vendors. Requests to provide MSIA with the relevant clauses from these contracts have been denied.

NEHTA Response 9:
The MSIA is requesting access to contracts in place with individual healthcare organisations and vendors. Providing this sensitive information to a third party is not appropriate.

Responses to MSIA Testimony – Senate Inquiry into PCEHR (6 Feb 2012) and Written Submission to Inquiry

Issue (quoted from Testimony transcript or written submission)	Response
"the PCEHR program is characterised by risks to patient safety even before development has been completed" - *testimony*	NeHTA has a Clinical Safety system in place to assess all NeHTA Standards and Specifications for PCEHR as they are planned. The need to assess the various products when they are acting together and in Clinical usage has been identified as being required throughout the entire process. Hence clinical safety is embedded into everything that we do, from having a dedicated clinical safety team within NEHTA to having 60 clinical leads working with NEHTA providing extensive, real world clinical input into all our work. NEHTA uses a specific clinical safety management tool (BT Sentry) to track and manage any clinical safety issues that may arise.
"The MSIA has previously requested access to NEHTA safety assessments, which NEHTA has consistently refused. "…"Starting back with the health identifiers service, we were assured by NEHTA that a full safety assessment had been made and we assumed that there was a report available of that. We have asked for that consistently for over two years and it has not been provided..." "More recently we have been asking for safety reports on the PCEHR implementation strategy and specifications, and again such safety reports have not been available" - *testimony*	As stated in the past, NEHTA has not released any reports to date, as it is important for "point in time" data not to be taken out of context or conflated with a later date. At no time has the HI Service and its capabilities been released into service without a "safe assessment", for the purposes intended in its usage. The clinical safety assessment process at the time that the HI service was developed was exposed to the various groups involved in its validation. A summary of the methodology will be made available after it is reviewed by our partners and the HI service Administrator (DHS). It will incorporate an updated assessment of the safety case for the HI Service DoHA has a written brief about Clinical Safety. The methodology and validation is planned with our Stakeholders. MSIA have sought safety assessments and reports for the HI Service at various stages during that service's development and operational lifecycle. NEHTA has fully disclosed the testing and assessment methodology for the HI Service, the results of testing and a summary of safety assessments in a personal briefing to the MSIA leadership, during a regular engagement update in January 2011. (NEHTA has compiled a pack of the current safety assessments and can provide the presentation material from January 2011 also)

	Within weeks of the above presentation, DHS hosted MSIA members to visit and "walkthrough" the DHS physical IT environments to demonstrate how the testing assurance regime is conducted. The MSIA CEO also has a paper detailing a summary of work and the methodology used within NeHTA. This system of assessing Clinical safety and the processes before the assessment, in plan and build phase of the products and indeed at the point of sign off as ready for the market are benchmarked. A recent review was conducted by BT, one by the University of NSW and another by Ernst and Young. Subsequent benchmarking is also underway by the Australian Commission of Quality and Safety in Health. On-going validation is planned with Clinical groups to show them the methodology and a view of the Clinical Safety framework. This is not an easy process to learn from volumes of technical notes which read out of context and in isolation would be time consuming, confusing, unhelpful and indeed subject to erroneous interpretation.
"We have had concerns about the underpinnings of the PCEHR – the health identifier services – safety for some time…it has become apparent only in recent months…that in fact those safety concerns cannot be addressed without a significant change in the specification" o An independent technology assessment committee looking at the issues of organisational and provider identifiers came to the conclusion that, in its current form, the service could not be operated safely… NEHTA's clinical safety unit was also asked for an assessment. After some time, they also endorsed that conclusion… That has meant that access to organisational and provider identifiers is not possible electronically in the current state" o "A patient's identifier can in fact change under a number of defined circumstances. When that change happens, there is no mechanism for Medicare notifying practices or practitioners of that change in	NEHTA disagrees this is a design flaw. As part of the design and development of the HI legislation and HI Service the clinical community was extensively consulted on privacy issues pertaining to the disclosure of healthcare provider identifiers (HPI-I and HPI-O). Based on this consultation the privacy settings were for an "opt-in" model for disclosure of the HPI-I and HPI-O to the healthcare community. Since the go-live of the HI Service, stakeholder feedback has been to revisit this setting to help facilitate the discovery and verification of healthcare provider identifiers in health information transactions. NEHTA, DHS, and DOHA are currently investigating options for enabling this request but must consider both legal and privacy reviews, and the views of stakeholders in the medical community, before any changes are made. The second issue raised by MSIA relates to the management of duplicate IHIs. They state that resolution of a duplicate can result in that individual's identifier changing. This statement is false. Duplicate management processes are well defined and implemented by DHS as Service Operator. More information on how duplicates are managed is available in Appendix 1.

identifier. Consequently, it becomes impossible to validate that identifier electronically against the service"	
"The Australian Medicines Terminology (AMT) has serious issues due to changes that have occurred whilst it was in the NEHTA process that are to do with its correctness and its utility" - *testimony*	Any statement that the AMT is not correct is false. The AMT goes through rigorous verification and validation processes before it is released. The eHealth ICT Implementation Committee was briefed in May 2011 on all the safety steps undertaken by NEHTA before an AMT release and Dr. McCauley was present at this meeting.
"We already have medicines terminologies in use in the system. They are provided by companies like MIMS, HCM and others. They have said, 'Why would we change from using a medicines terminology that we understand and has proven safety and quality for another that is of unknown quality, unknown safety and introduces a whole range of new issues" - *testimony*	The AMT is the nationally agreed terminology for the identification of medicines in electronic health systems. It delivers unique numeric identification and standardised descriptions of brand (trade) and equivalent generic (medicinal) products along with associated components that are supported through methods that accurately describe medicines. The key benefit of AMT is that it enables interoperability between systems. These outcomes cannot be achieved by proprietary drug databases like MIMS and those used by vendors such as HCN, which may work within a specific application but are not interoperable with other systems on a national level.
"The Australian medicines terminology, which is a NEHTA work item, has been implemented in a trial in one system. It is not used across the sector. It is not generally available. The transition from the current usage of diverse terminology to a single terminology is a very substantial piece of work that is not going to occur before 1 July" - *testimony*	The AMT was first released in 2007 and is now used in commercial software and deployed in 11 hospitals in Victoria within Cerner's Millennium software. These are not trial systems. Since the introduction of the systems using AMT into these sites, preliminary results show major reductions in prescription errors, so it is incorrect to say that these implementations are not meaningful. Contrary to the statement that AMT is not generally available, in fact the AMT is released every month, free of charge by NEHTA, so is widely available.
"Ernst & Young have recently been asked to review the AMT again to assess whether it is fit for purpose" *-testimony*	This statement is false. Ernst & Young has not been engaged, to NEHTA's knowledge, to conduct any such review.

Responses to MSIA Testimony – Senate Inquiry into PCEHR (6 Feb 2012) and Written Submission to Inquiry

"*in response to question from Senator McKenzie on how the MSIA suggests making NEHTA more accountable for its services and activities*)" "Without removing the cloak of secrecy and lack of accountability that currently covers NEHTA's activities, I believe that is almost impossible "…"It is totally a structural issue. It really comes back to the way the board is constituted"- *testimony*	NEHTA is governed by a Board of Directors which consists of the CEOs and Director-Generals of the nine Australian State, Territory and Commonwealth Health Departments, plus two independent directors, one of which holds the position of Chair. The NEHTA CEO also appears before Senate Estimate hearings to provide additional transparency, although there is no requirement to do so. Further accountability measures include financial accountability and public reporting, internal governance and reporting, and feedback loops between NEHTA and stakeholder reference groups on the NEHTA work program. See Appendix 2 for more information on NEHTA's overall governance arrangements.
NEHTA a "toxic workplace": o "In evidence before this committee the CEO of NEHTA admitted that their turnover rate for staff is close to 30 per cent per annum, which is extraordinary. Our information is that in the current financial year this climbed to closer to 40 per cent. There is no published organisational chart of NEHTA; the joke in the industry is that it would take too much time to keep it up to date" o "There have been losses from NEHTA's management structure in very significant areas over the last six months. I classify the four pillars of e-health as standards, security, terminology and safety, and in each of those areas the managers have disappeared from NEHTA under extraordinary circumstances" o "There have been allegations that have been aired in front of this committee about bullying in the workplace at NEHTA. We believe there is an active and ongoing investigation into that, which is actually more extensive than appears to have been agreed to by the	This statement by the MSIA is not supported by fact. Moreover, previous claims by MSIA that NEHTA is a hotbed of bullying and harassment were discredited after Workcover conducted an audit and had no findings against NEHTA. Staff members at NEHTA are committed to continuing the hard work required to deliver eHealth for Australia. NEHTA is committed to its organisational environment and its people, continuously monitoring employee feedback and adjusting workplace strategies when necessary. NEHTA utilises highly qualified staff from a small local resource pool, and is reliant on a large network of external stakeholders and partners to be successful. This environment poses challenges to retaining staff at the levels enjoyed by governments. For specific deliverables or parts of the work programme, NEHTA requires an agile workforce made up of specialised technical experts over different periods of time. Information Technology professionals are in high demand across all sectors and NEHTA competes in the employment market for this talent. As an organisation NEHTA has experienced rapid growth due to its evolving remit and focus. Further to the recruitment process, staff performance is formally managed twice each year through formal review processes.

CEO in his testimony here" o "There are concerns about the competence of the NEHTA personnel. The people in charge of the rollout of the IT implementations have no experience in either IT or health" o "I can tell you from my interactions with many of the staff that the morale within NEHTA, which again the CEO of NEHTA was asked to comment on, is at an all time low." *-testimony*	
"The current implementation program that is being targeted for 1 July is extremely complex with a lot of very complex data defined in the clinical documents that we are all expected to exchange and share through this personally controlled electronic health record. A feasible solution for 1 July could simply contain images of the reports that are currently generated by various health systems: the discharge summaries, the event summaries, referrals" – *testimony*	This statement is not supported by the software industry, including members of the MSIA with which NEHTA engages regularly. Although the task of building the specifications is not trivial, it has proven to be within the capability of typical software vendors, both large and small. NEHTA is working with software vendors to implement NEHTA specifications and software vendors have worked successfully with NEHTA on integrating the specifications.
"our fourth key issue is that industry has lost confidence in NEHTA's ability to deliver this program. There is evidence of a lack of probity, ineffective governance and an inability to deliver targeted programs" - *testimony*	This statement is not supported by the industry. Since the Senate hearing NEHTA has been contacted by numerous members of the MSIA and broader industry to distance themselves and their organisations from Dr. McCauley's testimony. NEHTA is committed to and actively working towards the timelines agreed with the sector which would see consumers able to register for a PCEHR on July 1. This commitment is apparent in our approach to developing specifications collaboratively, ensuring ongoing assurance and maintenance of these specifications, pursuing formal

	Standards publication based on suitable candidates, adopting and profiling existing standards and supporting change and adoption programs to realise the PCEHR's declared functionality and plans. Further detail is available Appendix 3.
(*in relation to the issues identified around access to provider and organisational identifiers*) "The committee charged with this has put forward recommendations for changes to the health identifier service for it to be modified. However, the committee has been provided with no information as to how those recommendations are being addressed or any time frame in which the health identifier service specification may be changed and implemented to address those concerns" - *testimony*	This statement is not supported by fact. All issues, without exception, raised by stakeholders about the HI Service are assessed and where necessary, addressed. The HI Service Operator provides regular briefings on the HI Service at monthly *eHealth ICT Implementation Committee* meetings, which Dr. McCauley and the MSIA attend. An update on a change request of interest to this Committee was also provided by the HI Service Operator at a recent Committee meeting. For a detailed example of how these issues have been addressed, please see Appendix 4.
"with less than six months before the PCEHR program is scheduled to go live, the Department of Health and Ageing has not provided a sustainable, commercial model that will support the national e-health program in the long term" – *testimony*	This statement is not supported by fact. Ongoing support of the PCEHR System is the responsibility of Government and NEHTA is aware that an Operational Blueprint is being developed that will set out how operations will be managed after the system is launched.
"There needs to be a Clear definition of the scope of the national infrastructure partner relative to other software systems, including local PCEHRs and conformant repositories, to facilitate planning and investment by the software industry and healthcare providers" - *written submission*	NEHTA has held many sessions with the sector to provide information on the PCEHR scope. These include vendor briefings, webinars, as well as meetings between DoHA and the MSIA. In addition, the concept of operations document clearly describes the nature and form of the PCEHR system, including the respective functions of the national infrastructure services and those of registered portals and repositories.
"Consider a "consenting adults" model where software that	All software, including GP desktop vendors and sidebar products, must pass through the same

acts in a parasitic way is tested with its "host" for all Conformance, Compliance and Accreditation processes. Where such inherently unsafe software has been used there should be a post deployment review to ensure that patient safety and identification has not been compromised"- *written submission*	Conformance, Compliance and Accreditation process prior to being able to connect to the PCEHR. They are currently required to do so for access to the HI Service as well and they must meet all the mandatory HI software conformance requirements. Testing is done via a third party via National Association of Testing Laboratories (NATA) accredited test laboratories. In relation to the PCEHR CCA testing, these test conditions are planned to include a clinical safety review of the interfaces used by clinicians to prepare documents for the PCEHR.
"Reduce the scope of the 1 July 2012 release of the program (Release 1) by deferring elements that are not sufficiently mature or not sufficiently reviewed to ensure patient safety (for example, Australian Medicines Terminology, Health Terminology (SNOMED), Consolidated View, etc.)" – *written submission*	The specifications are considered fit for purpose to guide software developers and implementers, and have been successfully used by the NIP and software vendors contracted to implement NEHTA specifications. NEHTA has communicated through tiger teams, through the regular vendor webinars and through release notes and documentation of the status of each specification. The use, presence and role of standards for Clinical Terminologies are clearly described in the specifications, along with endorsed approaches to agreed conformance "levels", which will help support adoption.

Responses to MSIA Testimony – Senate Inquiry into PCEHR (6 Feb 2012) and Written Submission to Inquiry

Appendix 1 – Duplicates and Replicas – Further Information

The MSIA submission incorrectly raises issues about the safety of the Healthcare Identifiers Service which are based on misconceptions of the system design in relation to the assignment, management and retrieval of Individual Healthcare Identifiers (IHIs).

The submission asserts that a person's IHI can change or new IHIs are issued under certain circumstances, in particular when their date of birth or gender record changes rendering the IHIs unusable as it would not be able to be matched with the person's demographics and therefore irretrievable and unable to be validated. The submission appears to confuse the management of demographic changes within the HI system with the management of duplicates.

A correction to the patient's date of birth or gender changes does not result in the assignment of a new IHI. IHIs are assigned when a person enrols in Medicare or DVA and others seeking healthcare in Australia such as individuals living or residing in Australia but not eligible to claim Medicare benefits or register with DVA. Where a person's Medicare details are changed (for example their date of birth or gender reassignment) they will continue to utilise the same IHI. Even when an individual is transferred to a new Medicare card their IHI would remain the same.

The legislation does provide for a person to be assigned another IHI when applying for a pseudonymous IHI. The pseudonym solution introduced the ability for individuals (persons who receive healthcare) to apply for an Individual Healthcare Identifier (IHI) under a pseudonym. Pseudonym IHIs are for individuals who feel they need to conceal their identity due to concerns for their personal safety or information when seeking healthcare. The solution ensures pseudonym IHIs are completely separate from individuals' existing records in the HI Service or Medicare systems. In the case of pseudonym IHIs, the healthcare sector would not be aware that a record was a pseudonym. This was designed to protect individual's privacy, as per the requirements of the legislation.

At times a Medicare record can be created for the same individual. The most likely circumstance for more than one Medicare record to occur is human error. If this occurs, then the individual will have two IHIs. To mitigate the chances of this occurring DHS have system controls in place, training and education for staff, and continual monitoring of data quality. Where issues are identified they are resolved by a specialist team on a daily basis with 100% Quality Assurance. NEHTA receives monthly reports from the System Operator monitoring the uniqueness of IHIs.

If two IHIs exist for an individual this is called a duplicate. A new IHI is not assigned if a duplicate record is found. Where duplicate records are found they are linked and categorised as primary and secondary records. The primary record is given an active status in the HI Service and the secondary record a resolved status. Any future search by a healthcare professional on the secondary record will return a message advising that the IHI has been resolved and the primary number should be used. This information is provided to alert the medical practice to check the information they are holding for the individual

in their practice management systems. The IHI audit histories of the two records are also linked. Where it is determined that an IHI has been accessed by an external source the individual is to be notified of changes to their IHI. To date this has not occurred.

Duplicate IHIs do not create risks that do not already exist today. Healthcare providers today deal with duplicate records in their systems. Duplicate records should not be confused with multiple IHIs, which are possible should the individual choose to have a pseudonym IHI. Multiple IHIs are a result of consumer choice.

Replica IHIs are not tolerated within the HI Service. No replicas have been found in the HI Service since commencement of the Service on 1 July 2010. Robust systems are in place to immediately identify a replica should it arise. Should a replica be found new IHIs will be assigned to the affected records. Where it is determined that an IHI has been accessed by an external source the individual is to be notified of changes to their IHI. Replica IHIs do not create risks that do not exist today; healthcare providers today deal with replica records in their systems.

Appendix 2 – NEHTA Governance Arrangements

The NEHTA governance framework provides the structure for effective management and decision-making and provides a strong basis for accountability and advancement of the NEHTA work programme.
NEHTA is a company limited by guarantee and as such is governed by the rules and regulations of the Corporations Act 2001, as administered by the Australian securities and investments commissions.

NEHTA was established by all of the health ministers of Australia and as such the members of NEHTA are all of the State and Federal Government Health Departments. The members are represented by the CEOs and Director-Generals of all the health departments across Australia, as funders of NEHTA.

The NEHTA Board of Directors

The company is governed by a Board of Directors which consists of the CEOs and Director-Generals of the nine Australian State, Territory and Federal Health Departments, plus two independent directors, one of which holds the position of Chair.

The NEHTA Board sets the strategic direction and overall governance framework under which NEHTA operates. The Board also establishes and mandates NEHTA's work programme on an annual basis.

In order to assist in the day to day operation of the company the Board have established four Board sub-committees:

1. Audit Committee
2. Finance Committee
3. Risk Committee
4. Remuneration Committee

The Board and the sub-committees meet a minimum six times per year to review and discuss the progress of the NEHTA work programme towards the achievement of the NEHTA objectives.

NEHTA, as a company, also has a constitution which provides specific details of governance as determined by the members and directors. The NEHTA Chief Executive is charged with the responsibility of enacting the Board's decisions. The NEHTA CEO enacts his responsibilities through the NEHTA executive leadership team.

Responses to MSIA Testimony – Senate Inquiry into PCEHR (6 Feb 2012) and Written Submission to Inquiry

In accordance its constitution, the corporations act and overall good governance NEHTA undertakes a full external independent audit annually. NEHTA has also engaged an independent review of its internal control processes and functions as well as regularly undertaking independent reviews of its work programme to ensure it continues to align with stakeholder expectations.

The CEO is also the custodian of the NEHTA Strategic Plan which consists of a number of strategic initiatives which together form the NEHTA programme of work.

The NEHTA Strategic Plan and work programme involve a number of key stakeholders across Australia. In order to ensure that NEHTA's programme of work is fit for purpose and meets the objectives and outcomes NEHTA regularly engages with these stakeholders. In particular NEHTA has established a number of programme reference groups, the stakeholder reference forum, the Clinical Leads forum, and the CIO Forum. The input and contribution of these stakeholders is critical to the success of NEHTA.

Funding at NEHTA

NEHTA is funded by the Australia Council of Australian Governments (COAG).

The funding awarded by COAG is shared on a specified formula upon which the Commonwealth provides 50% of NEHTA's funding and the other 50% is contributed to by the other States and Territories on a ratio commensurate with their population. Irrespective of the funding formula all company members of NEHTA enjoy equal voting rights at the board level.

Financial Governance at NEHTA

NEHTA has traditionally been funded on a triennial basis through COAG. This funding is typically broken down by year and by work programme. Each year NEHTA undertakes a comprehensive planning process whereby each project and programme puts together their proposed work programme for the ensuing 12 months, and provides a list of all of the deliverables expected for delivery in that 12 months.

Once the work programme has been prepared a budget is then established which lists the financial resources needed to meet the requirements of the work programme. This must be in accordance with the funding provided by COAG. During any financial year the NEHTA finance team prepare monthly reports which track the actual financial performance against budgets.

In addition to this monthly reporting, the budgets are reviewed in accordance with the actuals reporting and the forecasts updated.

A full set of financial reports are provided to the Finance Committee and the Board at every Board meeting.

NEHTA is also subject to public reporting obligations under the Corporations Act.

Internal Governance at NEHTA

In order to better coordinate the complexities associated with achieving integrated health outcomes NEHTA has established programme boards for Solutions Development and the PCEHR which provide delivery governance over the work programme. The programme boards are supported by the Programme Management Office (PMO) to ensure coordinated governance arrangements and progression towards best practice management.

NEHTA has also established project boards to govern the delivery of specific project outputs required by each of the programmes in line with PRINCE2 methodology which was adopted by NEHTA in 2009.

NEHTA continues its risk and issues governance through the Risk Management Committee. This group, acting on behalf of the full Management Review Group, meets regularly to review strategic and programme risks to ensure that mitigation plans are appropriate and being actioned.

A number of governance bodies operate across NEHTA, and need to interconnect in a consistent manner. NEHTA has established project boards to govern the delivery of specific project outputs required by each of the programmes.

- The programme boards for P&SD and PCEHR have similar attendance but different focus, ensuring all issues and escalations are addressed accordingly
- Programmes have their own unique structure and governance to meet needs e.g. PCEHR has an integrated governance model with DoHA due to the managing agent role.

Stakeholder Engagement

NEHTA also works very closely with its stakeholders and has developed a number of reference groups and forums to establish regular consultation and collaboration, these groups include: Stakeholder Reference Forums, The National CIO Forum, the Clinical Leads forum, CTIRG, IAARG, CCRG, MMRG, DSRG, and a number of Tiger Teams. NEHTA also regularly engages with industry groups and leaders including the medical indemnity insurers and Privacy regulators and lobby groups. All these groups and bodies help inform determine the NEHTA Programme.

Responses to MSIA Testimony – Senate Inquiry into PCEHR (6 Feb 2012) and Written Submission to Inquiry

Appendix 3 – Collaborative Development of Specifications

The development of nationally consistent Standards publications for eHealth software and service delivery is a core principle underpinning NEHTA's work programme. It is a vital mechanism for ensuring the quality and consistency of domestic systems and effective alignment with international products and services.

NEHTA developed and is operating against a strengthened end to end process for the development and documentation of eHealth requirements and their manifestation in clinically safe, technically interoperable specifications, and has demonstrated the ongoing intention and commitment to take the standards components of these specifications through the formal Standards Australia processes.

NEHTA prepared a Specifications and Standards Plan to describe the PECHR Specifications to be developed, the approach to collaborative development and the schedule for release of the specifications. This plan was released to the market in November 2011 following approval form the Department of Health and Ageing, and with considerable input from Standards Australia, eHealth Standards experts and industry consultation.

Based on local and international experiences in eHealth Programs, NEHTA understands that successful implementation of the PCEHR will depend on robust, stable and timely specifications that are developed through a transparent consultative process, and adopt wherever possible existing standards, with a commitment to progress novel and appropriate specifications to full standards publications.

Importantly the plan articulated the requirements and strategy to manage change to specifications once they were released, and agreed the principles for change:

- Clinical Safety
- Legal requirements
- PCEHR and National systems readiness.

The core objective of the plan was to ensure that software developers and implementers would have an agreed set of logical and technical specifications to guide enhancement of their systems in order to participate in the PCEHR System.

The plan established the approach to enable software developers and implementers:

- To understand how they may participate in the development of the initial and ongoing versions of specifications (and related standards where relevant).
- To know when and how versions of specifications will be published.
- To be supported in their implementation of the specifications.

Appendix 4 – HI Service Issue Resolution

One example is a request by the CCA Governance Group that vendor software be able to interrogate the HI Service directly for HPI-Is, rather than accessing the 'opt-in' provider directory service. This issue was also raised by jurisdictional health CIOs in October.

NEHTA sought initial advice from DOHA to determine if the HI legislation would allow this, and informal advice provided confirmed that it should. NEHTA submitted a change request to DHS to implement this functionality in the HI Service, and is awaiting costings back from DHS.

In developing costings, DHS had sought advice from DOHA on the type of search matching permitted by the legislation (eg exact match), so the costing process is quite involved and includes ensuring proposed change requests are legal. In the meantime, NEHTA and DHS are working on an interim process to allow lead implementation sites to obtain HPI-Is before the functionality is delivered.

This example clearly demonstrates that NEHTA does not ignore changes to the HI Service that are raised by stakeholders, although stakeholder expectations about the speed in which changes are made to the Service are not always met due to the need to confirm that requirements are legal.