SENATE
COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Questions On Notice

Inquiry into Healthcare Identifiers Bill 2010 and Healthcare Identifiers (Consequential Amendments) Bill 2010

1. What funding is being provided to Medicare Australia to operate the HI Service?

Answer: As part of the COAG Decision of 28 November 2008 to fund the ongoing operations of the National eHealth Transition Authority (NEHTA) from 2009-10 to 2011-12, funding of $52.02 million (GST Exclusive) was earmarked for the operating costs of the HI Service from 2009-10 to 2011-12. The Commonwealth's share, according to the AHMAC cost-sharing formula, is $26.01 million over this period.

2. How many staff are working in the new E-Health Branch?

Answer: The Department has 8.2 ASL ongoing staff and 1 ASL non-ongoing staff in the E-Health Systems Branch.

3. How much funding has been allocated to the development of the Individual Electronic Health Records (IEHR) Business case?

Answer: The Department of Health and Ageing has been allocated $3.7m for development of the IEHR business case.

4. Can DoHA provide a copy of the National EHealth Strategy?

Answer: A copy of the National EHealth Strategy is attached: **Attachment 1**. This can also be accessed through the following link:
http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Ehealth+Strategy

5. A number of witnesses claimed stakeholders and consumers have not been engaged in Healthcare Identifiers developments - Can DoHA provide information about consultations on the Healthcare Identifier proposals?

Answer: On 13 July 2009, a discussion paper was released seeking comments on legislative proposals to support the establishment and implementation of unique identifiers for healthcare purposes and the privacy of health information. As part of this consultation, two stakeholder forums were held to allow detailed discussion of the proposals and eight consumer focus groups were conducted. Consultation closed on 14 August 2009, and over 90 submissions were received from stakeholders.

Further consultation, including the release of exposure draft legislation was undertaken from 20 November 2009 to 7 January 2010. Over 50 submissions were received.

Information, discussion papers and proposed legislation was made available on the Department's public website, and e-mailing updates and calls for consultation were sent to approximately 300 people and organisations on the Department's e-mail distribution list. Many of the organisations on the Department's e-mail list include bodies which represent various community groups and interests, and it is understood these groups distributed materials provided by the Department to their members.

The text of advertisements and press releases that accompanied the consultations and details of participation by organisations in both consultations are attached: **Attachment 2**.

A number of individuals provided submissions.

6. Can DoHA provide information about proposed communications strategy for the HI Service eg proposed start date and who is involved?

Answer: A joint communications strategy has been developed between the Australian, state and territory governments and NEHTA for the Healthcare Identifiers Service. The strategy will be led and coordinated by NEHTA and covers three phases:

Phase 1 – Design of the HI Service and development of supporting legislation
Phase 2 – Implementation of the HI Service and planning for use
Phase 3 – Promotion and Launch of the HI Service.

All jurisdictions, NEHTA, Medicare Australia and the Department of Veterans' Affairs are involved in the implementation of the strategy. A communications working group was established including participants from communications/coordination units in DoHA, Victoria and the ACT Health Departments and communications officers from DoHA, Medicare and NEHTA.

Phase 1 is almost complete. Phase 2 is scheduled to commence in March/April 2010 as well as planning for the promotion and launch of the HI Service (Phase 3), to support proposed commencement of the HI Service in July 2010.

7. Why are Aboriginal and Torres Strait Islanders (ATSI) Health workers not going to be included in the first roll-out of NRAS professions given the 'Closing the Gap' initiative so they can participate in the HI Service? How will they be issued with an HPI-I?

Answer: Only those healthcare providers that have an HPI-I or are authorised employees of an identified healthcare provider organisation are able to obtain identifiers from the HI Service. HPI-Is will be automatically allocated to health professionals registered with the National Registration and Accreditation Scheme. ATSI Health Workers have not been included in the first round of professions under the National Registration and Accreditation Scheme.

However, under the HI Bill, there are a range of ways through which ATSI health workers and other healthcare providers will be able to participate (including obtaining an HPI-I) which do not rely on their being nationally registered.

National Registration is not proposed to be the only criteria under which an HPI-I is issued. The regulations under the HI Bill will provide for classes of healthcare providers who may be assigned identifiers by the HI Service operator. It is envisaged that those ATSI health workers who are registered through a State or Territory registration body under a state or territory law or members of a professional association with uniform national membership arrangements will be able to be assigned a HPI-I. ATSI health workers will need to apply directly to the HI Service to be assigned a HPI-I.

8. What are NEHTA and Medicare roles and responsibilities in relation to the HI Service?

Answer: The National E-Health Transition Authority's (NEHTA) role is to design and develop national infrastructure for national healthcare identifiers. In 2007, NEHTA contracted the scoping, design, build and testing of the HI Service to Medicare Australia. NEHTA is responsible for project and contract management activities in relation to the design and development of the HI Service.

Subject to the legislation being in place, Medicare Australia will also be the initial HI Service Operator. In accordance with legislative and regulatory obligations, contractual arrangements and national policies issued by the Ministerial Council, the roles and responsibilities of the Service Operator will be to:

(a) assign identifiers to individuals (IHIs);

(b) collect and adopt provider identifiers (HPI-Is) that are issued to individual healthcare providers by Trusted Data Sources;

(c) assign HPI-Iso other individual healthcare providers where no Trusted Data Source exists;

(d) assign identifiers to healthcare provider organizations (HPI-Os);

(e) maintain healthcare identifier datasets and infrastructure;

(f) disclose IHIs and HPI-Is for authorised purposes to authorised users;

(g) establish, operate and maintain a Directory Service that will enable authorised users to search for and locate healthcare providers and facilitate communications and information exchange between them, such as referral, test orders and results;

(h) educate, train and inform healthcare providers and consumers about how the HI Service operates;

(i) manage relationships with participants in the HI Service and relevant data sources;

(j) provide advice, information and reports to the Ministerial Council and other organisations as directed, on the performance of the HI Service;

(k) seek advice and direction from the Ministerial Council on key issues facing the HI Service, and on issues which have implications more broadly for the introduction of electronic health services in Australia;

(l) respond to initial inquiries and complaints about the HI Service (complainants not satisfied with the response they receive from the HI Service Operator may raise their complaint with the relevant regulator).

9. It is alleged that NEHTA have not followed international standards for healthcare identifier implementation – Is the Government aware of this standard and why it has not been followed – if it has not?

Answer: The Department understands that NEHTA has provided the Committee with a detailed explanation of its processes for considering and adopting relevant standards.

10. More than 30 of the recommendations in the Privacy Impact Assessments (PIA) undertaken for NEHTA in relation to the HI Service have not been taken up – which ones and why not?

Answer: There were a total of 74 recommendations across the three PIAs. NEHTA:

- referred 25 to Government;
- stated that five were no longer applicable e.g. use and disclosure of IHIs before activation;
- declined to support three outright (allowing HPI-Os to assign a single IHI to all anonymous patients; prohibiting batch downloads; and allowing address details for HPI-Is and HPI-Os to be in audit logs).

Details of the NEHTA responses is attached: **Attachment 3**.

A link to the information about the PIAs on the NEHTA website is:
http://www.nehta.gov.au/connecting-australia/privacy/pias

Of those referred to Government, only one has not been addressed in the HI Bill. This is the proposal that there be specific provision in the HI Bill for a data breach reporting regime on the HI Service. The adoption of data breach reporting as part of general privacy law is to be considered by the Department of Prime Minister and Cabinet in its second stage response to the Australian Law Reform Commission Review on Privacy and, if implemented would apply to the HI Service in respect of healthcare identifiers as well. It is not considered appropriate to impose this requirement solely for the HI Service at this time.

Details of the Commonwealth action in response to the PIA recommendations is attached: **Attachment 4.**

11. Healthcare Identifiers Bill 2010, Section 4(2) – This Act does not make the Crown liable to be prosecuted for an Offence – What does s4(2) mean? Why is the Crown treated in this way?

Answer: Under the provisions of the HI Bill, the Crown in right of the Commonwealth, of the States and of the ACT and NT, and of Norfolk Island are bound by the provisions of the HI Bill, and must comply with any relevant provisions in the Bill. However the Crown will not be subject to prosecution

The law on, and the policy in relation to, Crown liability is summarised in the Commonwealth's *A Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers* (at pages 32-33). It states:

> *As a matter of policy, the view has consistently been taken that criminal responsibility should not be imposed on the Crown under Commonwealth law. Where legislation is expressed to bind the Crown this should be qualified by a statement that the Crown is not liable to prosecution for an offence against the Act. (This is for the avoidance of doubt: even where legislation is expressed to bind the Crown, this has generally been considered insufficient to impose criminal responsibility upon the Crown.)*

The Guide is available at:
http://www.ag.gov.au/www/agd/agd.nsf/Page/Publications_GuidetoFramingCommonwealthOffences,CivilPenaltiesandEnforcementPowers

12. Healthcare Identifiers Bill 2010 - Clause 15(2)(b) and clause 26(2)(b) provide that it is not an offence when disclosure of a healthcare identifier has been authorised under another law – what is the meaning of 'another law' in these clauses? Why is it not more narrowly defined?

Answer: Provision for other uses or disclosures of personal information (including health information) to be authorised by law is a standard feature of privacy laws.

Clauses 15(2)(b), and 26(2)(b) in the HI Bill adopt this approach in relation to healthcare identifiers. Given that the identifiers will be associated with health information it is appropriate that the same approach is adopted for identifiers as applies to that health information.

The Australian Law Reform Commission considered such authorised by law provisions in its recent review of Australian privacy laws and concluded that the Privacy Act should not fetter government's discretion to require certain information to be handled in a particular way. Another law will include Commonwealth, State or Territory law.

The National Partnership Agreement on E-Health sets out arrangements for Ministerial Council involvement in the development of relevant laws.

13. Why are the some aspects of the HI scheme to be provided for through regulations rather than in the legislation – eg change of service provider and right of review and offences against the regulations.

Answer: Regulations are proposed to provide flexibility to deal with changed circumstances more readily than might be possible through legislation. At the same time there are other requirements that the Bill imposes that ensure any regulatory proposals are constrained.

In relation to changes to service operator, clause 6, Medicare Australia will be established through the HI Bill as the initial Service Operator. The HI Bill defines the 'Service Operator' as Medicare Australia or another entity prescribed in the regulations.

The HI Bill imposes an obligation on the Minister responsible for the legislation to consult with the Ministerial Council prior to making regulations to support the operation of the HI Service. This would include any decision to change the Service Operator from Medicare to another entity. Regulations would be tabled in both Houses of Parliament, and would be subject to disallowance.

Any new HI Service Operator would still be subject to the requirements and processes established by the HI Bill and regulations including;

- oversight by the Federal Privacy Commissioner;
- confidentiality requirements and penalties for staff of the HI service operator;
- processes for assigning and disclosing healthcare identifiers to authorised providers for authorised purposes;
- reporting to the Ministerial Council and having those reports tabled in Parliament; and
- complying with directions issued by the Ministerial Council.

Allowing for the prescription of a different service operator through the regulations will provide a simpler means by which responsibility could be transferred were this to be determined to be warranted, whether as a result of changed arrangements in the delivery of Commonwealth services or ehealth system developments.

Clause 9(5) allows regulations to provide for review of decisions to assign identifiers. This is because the circumstances under which identifiers are to be assigned vary and flexibility in allowing for review was considered to be required to avoid imposing review where it was not warranted based on the nature of the decision and the possible detriment.

As agreed by COAG in November 2008, the identifier assigned to healthcare recipients (IHI) is to be universally allocated to all individuals receiving healthcare in Australia. Individuals will not need to do anything to be allocated an IHI and a decision to assign an IHI is procedural. Review of such assignment is not envisaged.

The arrangements under which identifiers are to be assigned to classes of providers are to be set out in regulations. The circumstances and arrangements for assignment of identifiers to provider organisations and individuals are different and may vary depending on the outcome of consultations on the regulations. At this stage the decisions to assign identifiers are considered essentially procedural and any detriment that will flow minimal, but allowing for the regulations to provide for review will enable such processes to be put in place if that is considered to be warranted, without this being imposed unnecessarily through the legislation.

Clause 27 provides for offences to be set out in the regulations and such offences being limited to 50 penalty units. Providing for the regulations to specify offences is considered necessary to allow differences between consequences from different situations and provide flexibility in considering what the offences should apply to under the regulations. The consultation on the regulations will invite feedback on the appropriateness of different offences proposed.

ADDITIONAL QUESTIONS RAISED DURING THE HEARINGS THAT REQUIRE RESPONSE

A. What privacy protections are in place to support the appropriate use of healthcare identifiers?

The combination of technology controls (such as agreed access and security controls), specific limits set out in the Healthcare Identifiers Bill and existing privacy laws will provide strong privacy protections for healthcare identifiers.

There will be clearly established legislative limits on the adoption, use and disclosure of healthcare identifiers. Healthcare identifiers can only be used for health information management and communication as part of the:

- provision of healthcare to an individual;
- management, funding, monitoring or evaluation of healthcare;
- provision of indemnity cover for a healthcare provider;
- conducting research that has been approved by a Human Research Ethics Committee; or
- lessening or preventing a serious threat to an individual's life, health or safety or to public health or public safety.

These permissions relate specifically to healthcare identifiers - they do not authorise the sharing of personal or health information that may be linked to particular identifier. Use or disclosure of personal or health information would still need to be undertaken in accordance with existing privacy and health information laws in each jurisdiction.

Healthcare providers who are identified with an individual healthcare provider identifier (HPI-I), or an authorised employee, can access the HI Service to obtain the IHI of a patient being treated.

The system design does not allow "browsing" of records – a request by an authorised healthcare provider for a patient's identifier will only reveal an IHI when there is an exact match with patient information provided by the healthcare provider. Each time a record held by the HI Service is accessed, the details of the requestor and when the request was made will be recorded in an audit log.

The Federal Privacy Commissioner will monitor the operation of the HI service by Medicare Australia and handle complaints against the Commonwealth public sector and private sector organisations.

B. How are Healthcare Organisations defined

All organisations that provide healthcare services will be able to apply for a HPI-O.

As part of establishing their eligibility to be assigned a HPI-O, an organisation will need to provide evidence to the HI Service that it is a legal entity and that it employs or contracts one or more individual healthcare providers, or that it is a sole trader, for the purpose of providing a health service.

Organisations must also have one or more people undertaking specific roles designed to ensure that the Service Operator is kept up to date with information about the provider organisation.

C. How does the legislative framework prevent function creep? What will stop future governments from using healthcare identifiers for other purposes?

Healthcare providers and related entities may use and disclose healthcare identifiers, namely for communicating and managing health information as part of the:

- provision of healthcare to an individual; or
- management, funding, monitoring or evaluation of healthcare; or
- provision of medical indemnity cover for a healthcare provider; or
- conducting research that has been approved by a Human Research Ethics Committee.

Healthcare identifiers can also be used or disclosed to lessen or prevent a serious threat to an individual's life, health or safety or to public health or public safety.

Healthcare identifiers will only be used for these permitted purposes. Any use or disclosure which does not fall within the permitted purposes will be prohibited and will be subject to offence and penalty provisions outlined in the legislation.

The limits apply equally to government and private sector organisations and are designed to prevent healthcare identifiers being used for other programs such as health or welfare payments or in relation to private health insurance.

Any broader uses of healthcare identifiers would require legislative change, involving appropriate Parliamentary scrutiny and consultation with the Australian community.

D. Are the legislative review timeframes sufficient?

The National Partnership Agreement on E-Health (E-Health NPA) and the HI Bill provide arrangements for review of the HI Service. The E-Health NPA provides for the independent review of the HI Act and the implementation, operation, performance and governance of the HI Service following two years of operation. The review is to be completed and a report provided to the Ministerial Council by 30 June 2013.

As the roll-out of healthcare identifiers will be incremental, the HI Service is not expected to be operating at full capacity from 1 July 2010. It is expected that at the end of the first two years of operation, a thorough review of the operation of the HI Service, its functions and Medicare Australia's role as Service Operator would be able to be undertaken. An earlier assessment may not give the full picture of how the HI Service will operate or how healthcare identifiers will be used in the health sector.

The Privacy Commissioner will be responsible for undertaking an annual report on the compliance and enforcements activities in relation to the HI Service, specifically in relation to privacy. This will ensure that any privacy issues are identified on a more regular basis and can be appropriately addressed.

E. What are the complaints handling arrangements for healthcare identifiers? Are they sufficient? What appeals processes are in place?

The Federal Privacy Commissioner will oversight the operation of the HI Service and handle complaints against Commonwealth Government agencies and private sector healthcare providers where an individual believes their privacy has been interfered with. Complaints will be handled in accordance with existing complaints arrangements under the *Privacy Act 1988*.

The Privacy Commissioner attempts to resolve complaints on a case-by-case basis through conciliation. Depending on the particular complaint, some possible resolutions may include:

- An apology
- A change to the respondent's practices or procedures
- Staff counselling
- Taking steps to address the matter, for example providing access to personal information, or amending records
- Compensation for financial or non-financial loss
- Other non-financial options, for example a complimentary subscription to a service.

A matter may be referred by the HI Service Operator, the Privacy Commissioner, the Department of Health and Ageing or the police, to the Department of Public Prosecutions for consideration and possible prosecution.

An application for a review of a decision made by the Privacy Commissioner can be made where:

- A decision by the Privacy Commissioner not to investigate, or not to investigate further, a complaint under the Privacy Act is not legally correct; or
- A determination by the Commissioner following the investigation of a complaint is not legally correct;

Application for review of the decision or the determination is made to the Federal Court of Australia or the Federal Magistrates Court under the *Administrative Decisions (Judicial Review) Act 1977* (Cth).

The Court will not review the merits of the case but may refer the matter back to the Commissioner for further consideration if it finds the Commissioner's decision was wrong in law or the Commissioner's powers were not exercised properly.

In addition to handling complaints, the Federal Privacy Commissioner will also be able to conduct audits and initiate investigations.

Each state and territory is expected to nominate a local regulator to oversight the handling of identifiers by its state or territory bodies and to put these arrangements in place through legislation. The Commonwealth legislation will apply until a state or territory puts consistent safeguards in place for their public sectors.

Penalties for the intentional misuse of healthcare identifiers, such as inappropriate disclosure of information by the HI Service, healthcare providers or any other person, will be set out in Commonwealth, state and territory legislation.

F. Why has a universal model for the assignment of individual healthcare identifiers been adopted?

Any individual who receives healthcare services within the Australian healthcare system will be assigned a unique healthcare identifier. The HI Service Operator will automatically assign an IHI to individuals who are enrolled for Medicare benefits or have a Department of Veterans' Affairs (DVA) treatment card.

People who are not already registered with Medicare or DVA will be assigned a temporary identifier by the HI service when the person next seeks healthcare. The assignment process will be authorised by legislation rather than individual consent.

Authorised healthcare providers will be able to obtain a unique identifier from the HI service for their patient records without obtaining the patient's consent. The identifier will be added as a new field in a patient's record alongside the name and DoB details that a person's healthcare provider already holds.

The ways in which a healthcare provider uses or discloses information held in patient records, including the identifier, will continue to be regulated by privacy laws and professional obligations such as confidentiality. In practice this means that the transfer of information between healthcare providers using a healthcare identifier will ordinarily be with patient consent.

A voluntary model for assigning identifiers was considered, but was ultimately assessed as unworkable. Healthcare providers would have needed to maintain duplicate identification systems and undertake several additional steps at the point of care to manage individual decisions to participate or withdraw participation. In the case of an individual deciding to opt-out of the system, removing their identifier from information in provider systems would have proved extremely difficult.

G. Why can't this legislation wait until the legislative framework for the whole eHealth system is developed?

There will be immediate benefits from the introduction of healthcare identifiers in improving the existing methods of communication between healthcare providers. However, healthcare identifiers will also provide one of the key foundation elements of future e-health applications, including the proposed IEHR system. Healthcare Identifiers would need to be widely adopted before they would be able to support an IEHR system and the adoption of Identifiers will be incremental and could take several years.

Development of an IEHR system is a recommendation of the National Health and Hospitals Reform Commission. The government has been consulting on the NHHRC recommendations and is currently considering its response.

The design of any future national IEHR will be subject to further public consultation and consideration of privacy and legislative support requirements. Developing those final legislative requirements would be a complex and lengthy process and significant delays in realising the benefits of the Healthcare Identifiers would result if the Bills were not to be considered until IEHR legislative framework was developed.

H. Do software vendors and healthcare providers have the information necessary to start preparing for the roll-out of healthcare identifiers?

NEHTA and Medicare have released technical documents over the past several months and will continue to make these available as the legislative settings are made and the software design is finalised. For example, NEHTA published the foundation technical documents and specifications on its website in November 2010. These specifications include:

- The HI Service concept of operations
- HI Service business use case catalogue
- IHI business requirements
- HPI business requirements
- HI Serice glossary
- HI Service catalogue
- And others

Further technical documents and an online technical service operated by Medicare opened on March 1. This includes support for vendors to test their products, a test environment, test data and a Helpdesk. Technical documents accompanying this include:

- Developers agreement
- Test certificates (HPI-I, HPI-O, OMO, RO)
- Test data (individual, provider, organisation, Organisation Maintenance Officer, Responsible Officer)
- WSDL and XSD (schemas)
- NEHTA, AS, ISO standards
- Foundation Documents

The Technical Services Catalogue & Service Interface Specifications will be available in early April. These are available to any vendor who chooses to participate in the Medicare testing process.

I. How will individuals access the HI Service to view their personal information or the audit trails?

Individuals and their authorised representatives will be able to access demographic information held by Medicare Australia as part of the HI Service and an audit log of who has obtained their identifier from the HI Service. Individuals and their authorised representatives will also be able to obtain a person’s identifier from Medicare.

Access for individuals to the HI Service will be through existing Medicare Australia channels including web portal, telephone support or a Medicare Australia office.

J. What personal information will be associated with the IHI?

The IHI will be associated with a limited amount of identifying information such as name, date of birth, and sex. In some circumstances, further data may be required to ensure unique assignment or to assist with the use of IHIs such as: address, birth plurality and birth order, and aliases.

The HI Service will not collect or hold health information about any person.

K. What was achieved through the HealthConnect program?

The $98 million Health*Connect* Program represented a national partnership between the Commonwealth and state and territory governments. Its objective was to encourage the uptake and appropriate use of standards-based eHealth technology. States and territories have implemented needs-based projects to improve the safety and quality of clinical communications in their region.

ACT Health*Connect* completed a trial implementation of their eReferral project to over 40 GPs as well as targeted specialists and allied health professionals.

- By the end of June 2009, over 40 GPs were recruited to participate in the initial roll out of e-referral, the system had been developed and fully configured and user acceptance testing of the application and user training was completed. The system went live on 2 June 2009.

New South Wales Health implemented their Healthelink project which developed Electronic Health Records in hospitals in Greater Western Sydney and the Hunter Valley.

- 75,000 patients are currently participating in this project and the opt-out rate has remained stable at 4.5%.

The Northern Territory has a high rural and remote population and the implementation of a Shared Electronic Health Record and point-to-point secure messaging system in this area has allowed vital health care information to be shared by health care professionals.

- There are over 34,000 consumers registered to participate in the Shared Electronic Health Record, including 68% of the total remote indigenous population.

The South Australia Health*Connect* project developed a care planning system allowing secure connectivity, establishing systems between health providers.

- Over 1119 secure broadband grants have been provided to health care providers. A total of 1210 secure electronic messaging software packages have been allocated to Divisions of General Practice for distribution.

The Tasmanian Health Client Index (THCI) has been implemented in Tasmania. It is now operational and has received positive user feedback. An Electronic Discharge Summary project has been undertaken, and has gone live in hospitals State-wide. The Electronic Patient Care Record project, allowing electronic patient records to be completed in ambulances state-wide, has now concluded.

- 40 ambulances (100% of the fleet) were fitted with Electronic Patient Care Record equipment, and 210 trained officers are using the system on a regular basis. The program is currently operating in several community pharmacies (approximately 13) and the Pharmacy Guild is currently recruiting additional pharmacies. The Electronic Discharge Summary project has been rolled out in North West Regional Hospital, Launceston General, Mersey Hospital and Royal Hobart Hospital.

Funding

05/06	06/07	07/09
$31.8 million (GST exclusive)	$31.5 million (GST exclusive)	$34.7 million (GST exclusive)

Selected PIAC issues and draft responses

PIAC recommendation 1

That the Senate Community Affairs Legislation Committee recommend to the Parliament that debate and voting on the *Healthcare Identifiers Bill 2010* (Cth) and the *Healthcare Identifiers (Consequential Amendments) Bill 2010* (Cth) be postponed until the amendments to the *Privacy Act 1988* (Cth) in respect of health information privacy are enacted.

Comment: There is currently some inconsistency between privacy laws in the various Australian jurisdictions. However, the Bill provides additional protections that will apply to healthcare identifiers of individuals and organisations in all jurisdictions.

The HI Bill and regulations have been designed to operate in parallel with existing privacy and health information laws applicable at Commonwealth, State and Territory level.

The HI Bill only applies to healthcare identifiers and their use or disclosure. It does not apply to the health information which they will be applied to which will continue to be governed by information privacy laws in each jurisdiction. Should privacy laws change in the future – for example, as part of new national health information privacy arrangements – the provisions in the HI Bill and regulations would continue to operate in parallel with the amended privacy laws.

PIAC recommendation 2

That the *Healthcare Identifiers Bill 2010* (Cth) be amended to remove clauses 24(1)(a)(ii), (iii) and (iv).

Comment: The HI Bill already imposes stricter limits on the use and disclosure of healthcare identifiers that existing privacy laws do in relation to personal and health information.

Proposed clauses 24(1)(a)(ii), (iii) and (iv) of the HI Bill are necessary to provide for the legitimate use and disclosure of healthcare identifiers as outlined in those clauses. In the case of each sub-clause, use and/or disclosure of a healthcare identifier may be required because it is necessary to positively identify the individual in question. For example, an insurer providing professional indemnity insurance to a healthcare provider may need to confirm that the insurance is being provided in relation to a claim brought by a particular individual.

The provisions in the HI Bill do not allow the wider use or disclosure of the health information to which they are attached than is presently provided for under existing privacy laws. The HI Bill only ensures that where that health information is being used or disclosed as permitted by those privacy laws and is being done as part of the management or communication of health information within one of the permitted purposes in s24, the healthcare identifier can be used or disclosed with that health information.

PIAC recommendation 3

That the *Healthcare Identifiers Bill 2010* (Cth) be amended to provide healthcare recipients with the right to require the service operator to correct or annotate their healthcare identifier data held by the service operator from the date of system implementation.

Comment: The Privacy Act 1988 provides a right for any individual to correct or annotate their records under IPP7, s14. This provision will apply to any personal information held by the HI Service, relating to their healthcare identifier.

PIAC recommendation 6
That the Committee consider whether or not some or all uses and disclosures, other than to the healthcare recipient, of identifying information and/or healthcare identifiers of that healthcare recipient require individual consent.

Comment: The ways in which a healthcare provider uses or discloses information held in patient records, including the identifier, will continue to be regulated by privacy laws and professional obligations such as confidentiality. In practice this means that the transfer of information between healthcare providers using a healthcare identifier will ordinarily be with patient consent.

A voluntary model was considered, but was ultimately assessed as unworkable. Healthcare providers would have needed to maintain duplicate identification systems and undertake several additional steps at the point of care to manage individual decisions to participate or withdraw participation.

PIAC recommendation 7
That the *Healthcare Identifiers Bill 2010* (Cth) be amended to remove the reference of matters to regulation in clauses 6(2), 7, 9(5), 12(2), 14, 21 and 27 and replace them with express clauses dealing with the matters that are currently to be separately regulated.

Comment: Removing the regulation making power in the clauses recommended by PIAC will severely curtail the ability of the Service to respond to needs within the healthcare sector. This in turn would be likely to impact on the establishment and operation of the HI Service. For example, following the establishment of the HI Service, it may become apparent that additional access controls and security obligations are required on healthcare providers beyond those currently required under the Bill and draft regulations. Allowing obligations to be prescribed by regulation allows a flexible and quick response where necessary.

PIAC recommendation 9
That the Senate Community Affairs Legislation Committee recommend that the Government give urgent priority to informing the broader community of the proposed development and implementation of the Healthcare Identifiers Service and its key components and develop a community awareness strategy to be implemented at the time of the implementation of the Healthcare Identifiers Service to ensure healthcare recipients are aware of the Service and their rights in respect of the Service.

Comment: See DoHA response to a direct question from the Committee. Action is underway to develop a communications strategy to educate and inform stakeholders and the public about the HI Service

The strategy will include processes for raising awareness about the purpose and benefits of introducing healthcare identifiers and providing more detail about the privacy and legislative protections that will be put in place.

PIAC recommendation 10
That the Healthcare Identifiers Bill 2010 (Cth) be amended to include:

(a) specific obligations on the service operator and entities, expressly including healthcare providers, in possession of identifying information and/or healthcare identifiers to implement and maintain strong information security measures; and

(b) penalties for failure to ensure the security of healthcare identifiers and identifying information.

Comment: Information security has been a primary consideration in the design and development of the HI service. The HI Service will operate in conjunction with standardised authentication mechanisms and comply with international best practice for information security.

As the service operator, Medicare Australia is limited by the HI legislation as to its use or disclose healthcare identifiers and the information relating to these. The HI Bill also limits the uses and disclosures of healthcare identifiers as set out in s24. Existing privacy laws will also apply to information held by the service operator and providers in relation to the privacy and security to be maintained for personal information that is held.

PIAC recommendations 11, 12 and 13

11. That the words '… information for the purpose …' in subclause (b) of clauses 11(2), 13(2), 16(2) of the Healthcare Identifiers Bill 2010 (Cth) be amended to read:

'(b) … information;
for the purpose …'

12. That the words '… healthcare identifier for the purpose …' in clause 20(2)(b) of the Healthcare Identifiers Bill 2010 (Cth) be amended to read:

'(b) … healthcare identifier;
for the purpose …'

13. That the words '… use the healthcare identifier, or to disclose the healthcare identifier to a healthcare provider, for the purpose …' in clause 24(2) of the Healthcare Identifiers Bill 2010 (Cth) be amended to read:

'(b) … use the healthcare identifier; or

(c) to disclose the healthcare identifier to a healthcare provider;
for the purpose …'

Comment: Intent is clear. It is not necessary to modify.

PIAC recommendation 14

That the *Healthcare Identifiers Bill 2010* (Cth) be amended to remove the crown indemnity in clause 4(2) so as to ensure that if the service operator is an entity of the 'crown' it can be held liable for breaches of the legislation.

Answer: See response to a direct question from the Committee. The provision as drafted reflects current Commonwealth policy.

PIAC recommendation 17
That the *Healthcare Identifiers Bill 2010* (Cth) be amended either to remove clause 24(1)(b) or change the wording of paragraphs (b)(i) and (ii) to read 'serious **and imminent** threat'.

Comment: The provision reflects what is proposed to be adopted by the Commonwealth in its response to the ALRC Review of Privacy in respect of equivalent provisions that apply to personal information in the Privacy Act 1988.

PIAC recommendation 18
That the Healthcare Identifiers Bill 2010 (Cth) be amended either:

(a) by the removal of clause 26(2)(b); or
(b) by amendment of clause 26(2)(b) to read '… for a purpose that is expressly authorised under a prescribed law'

Comment: See response to direct question from the Committee.

PIAC recommendation 19
That the Senate Community Affairs Legislation Committee specify a prosecuting authority in respect of offences under the Act.

Comment: The penalty provisions in the HI Bill are all criminal provisions.

Under the *Director of Public Prosecutions Act 1983* (Cth), the Commonwealth Director of Public Prosecutions would be responsible for instituting proceedings against a person or organisation accused of committing an offence under the HI Bill.

Generally, where an Act provides for *civil* penalty provisions it is usual for the Act to specify which person or organisation is responsible for instituting proceedings in relation to those provisions. However, as the HI Bill contains no civil penalty provisions, it is not necessary to specify a prosecuting authority.

PIAC recommendation 22
That the definition of 'entity' in clause 5 of the Healthcare Identifiers Bill 2010 (Cth) be amended to include bodies corporate.

Comment: This suggested amendment is not required.

The definition of entity in clause 5 of the Bill relevantly states that entity means "a person".

Section 22(1)(a) of the *Acts Interpretation Act 1901* (Cth) provides (emphasis added):

> *22(1) <u>In any Act, unless the contrary intention appears</u>:*
>
> *(a) <u>expressions used to denote persons generally (such as "person</u>", "party", "someone", "anyone", "no-one", "one", "another" and "whoever"), <u>include a body</u> politic or <u>corporate</u> as well as an individual;*

The HI Bill contains no contrary intention that would displace section 22(1)(a) of the *Acts Interpretation Act 1901* (Cth).

Attachment 1

The National EHealth Strategy is attached as a separate document

1. ADVERTISEMENTS

July 2009 consultation

CONSULTATION ON HEALTHCARE IDENTIFIERS AND PRIVACY:

Proposals for Legislative support

To support development of the national e-health agenda, the Council of Australian Governments (COAG) has agreed to the development and implementation of unique healthcare identifiers for healthcare consumers, providers and provider organisations.

The legislative framework to underpin implementation of healthcare identifiers and the establishment of appropriate national privacy arrangements for health information is currently being developed collaboratively by Commonwealth, state and territory health departments.

Stakeholder and community views on the legislative proposals are now being sought. Your input will contribute to making the legislative arrangements robust and effective – protecting the privacy of personal information while achieving the healthcare benefits that can be gained through better sharing of health information.

A discussion paper on the legislative proposals is available at www.health.gov.au/ehealth/consultation or by calling (02) 6289 3919.

Submissions may be:

1. Mailed to:

    Healthcare Identifiers and Privacy Submission
    Primary and Ambulatory Care Division (MDP 1)
    Department of Health and Ageing
    GPO Box 9848
    CANBERRA ACT 2601

   OR

2. Emailed to: ehealth@health.gov.au

The closing date for comments and submissions is **5pm (AEST), Friday 14 August 2009.**

This is a collaborative initiative of the Commonwealth and all state and territory health departments.

(b) December Consultation on exposure draft legislation

CONSULTATION ON HEALTHCARE IDENTIFIERS: Release of Exposure Draft Healthcare Identifiers Bill 2010

To support development of the national e-health agenda, the Council of Australian Governments (COAG) has agreed to the development and implementation of unique healthcare identifiers for consumers, providers and provider organisations.

On 13 November 2009 Health Ministers affirmed their commitment to the introduction of national healthcare identifiers in 2010 and agreed to release draft legislation for establishing the Healthcare Identifiers Service for public comment.

Healthcare Identifiers are unique numbers that will be assigned to all healthcare consumers, providers and organisations. These identifiers will provide a new level of confidence when communicating patient information between healthcare providers and systems to improve the delivery of healthcare in Australia and build a foundation for future e-health initiatives.

The exposure draft Healthcare Identifiers Bill 2010, supporting documentation and a guide to providing comments on the draft bill is available from www.health.gov.au/ehealth/consultation or by calling (02) 6289 3919.

Comments may be sent to:

Exposure Draft Healthcare Identifiers Service Bill 2010
E-Health Branch
Primary and Ambulatory Care Division (MDP1)
Department of Health and Ageing

ehealth@health.gov.au

or GPO Box 9848
CANBERRA ACT 2601

The closing date for comments and submissions is **5pm (EDT), Thursday, 7 January 2010.**

This is a collaborative initiative of the Commonwealth and all state and territory health departments.

2. PRESS RELEASES

(a) July 2009 Consultation

Australian Health Ministers' Conference

First step taken towards national e-health system

13 July 2009

National consultations are set to begin on the legislative framework to underpin the governance, privacy and agreed uses for national healthcare identifier numbers essential to a secure national e-health system.

Healthcare Identifiers are unique numbers that will be given to all healthcare providers, healthcare centres and healthcare consumers. These unique numbers will provide a new level of confidence when communicating patient information between the myriad of private and government healthcare providers and systems.

To date there has been no single method of accurately and reliably identifying the patient receiving healthcare, the healthcare providers or the organisations managing care.
Mismatching of patients with their records and medical results is a documented problem for the health system. There is a clear link between avoidable patient deaths and poor medical records management.

All Australian residents will be allocated an Individual Healthcare Identifier (IHI) to support better communication between healthcare providers involved in patient treatment – but no patient will be forced to use it to access any health service.

The IHI service will be managed initially by Medicare Australia – a trusted and secure provider of dedicated health related services. This will be separate to its funding and claims functions. The IHI will not replace a patient's Medicare number, which is used for claiming government healthcare benefits.

The IHI service will hold only enough information to clearly identify the person. No clinical information or medical records will be stored in the IHI service and an IHI will not need to be declared for an individual to receive healthcare

The Australian Health Ministers' Conference asked for consultations to be held so that a broad range of perspectives can contribute to making the legislation robust and effective – balancing the privacy of personal information with the healthcare benefits that can be gained through better sharing of health information.

Consultations with key industry stakeholders will be held during July and a discussion paper detailing the legislative framework will be available online from 13 July to allow broad community input. The consultations on the drafting of legislation build on earlier consultations with key stakeholders about the recommendations in the Australian Law Reform Commission's report on its review of Australian privacy laws, including health privacy protections.

The Australian Health Ministers' Conference believes strong privacy protection for patient health information is fundamental to delivering high quality individual and public health outcomes.
The discussion paper can be accessed online at www.health.gov.au/eHealth/consultation from 13 July.

Media Contact: Minister Gallagher's office 0402 399 907 or Minister Roxon's office 02 6277 7220

(b) December 2009 consultation

10th December 2009

E-HEALTH TAKES IMPORTANT STEP FORWARD

The Rudd Government today released draft legislation that will assign a healthcare identifier number to health care providers and consumers – an important first step in building a secure e-health system in Australia.

The Rudd Government has worked closely with the states and territories to develop the exposure draft legislation, which is aimed at improving the health system's ability to effectively share patient information, while safeguarding patient privacy.

To date, there has been no single method of accurately and reliably identifying either the people receiving healthcare, the healthcare providers or the organisations managing care.

Mismatching of patient information has been an acknowledged problem in the health system.

These unique identifiers will provide a new level of confidence and accuracy when communicating patient information across and between private and government healthcare providers involved in providing care to patients.

Medicare Australia will be the initial operator of the healthcare identifier service. As a trusted government authority, Medicare has the national infrastructure, as well as the industry and community relationships, needed to securely deliver and maintain the identifiers.

People do not have to apply for an identifier: it will be allocated automatically to every Australian who is currently on a Medicare card or a Department of Veterans' Affairs treatment card. People who are not covered by these will be allocated their identifier on an individual basis. Use of the identifier would be strictly limited to healthcare with jurisdictional regulators including the Federal Privacy Commissioner providing independent oversight.

The draft legislation follows comprehensive consultations with stakeholders. The Australian Health Ministers' Conference believes strong privacy protection for patient health information is fundamental to delivering high quality individual and public health outcomes.

It is planned to have the healthcare identifiers becoming available from mid-2010 subject to legislation having been passed by the Australian Parliament. The exposure draft legislation and explanatory material can be found on the department's website at: www.health.gov.au/ehealth/consultation

The closing date for comment on the exposure draft bill is Thursday 7 January 2010.

For all media inquiries, please contact the Minister's Office on 02 6277 72

3. ORGANISATIONS THAT HAVE PARTICIPATED IN CONSULTATIONS

A. First consultation period –July/August 2009

July 2009 Pre-Consultation Meetings
Australian Medical Association
Australian Privacy Foundation
Consumers Health Forum
Electronic Frontiers Australia
Health Informatics Society of Australia
Liberty Victoria (also Access Card No Way)
Medical Software Industry Association

Attendance at Sydney Forum 30 July 2009
Aged Care Association Australia
ARAFMI (NSW)
Australian Association of Practice Managers
Australian Commission on Safety and Quality in Health Care
Australian General Practice Network
Cancer Voices Australia
Cancer Voices NSW
Department of Prime Minister and Cabinet
Family Planning NSW
Health Informatics Society of Australia
Health Information Management Association of Australia
Health Services Commissioner (ACT)
MDA National Insurance
Medical Indemnity Industry Association of Australia
National Coalition of Public Pathology
Network of Alcohol and Other Drug Agencies
Office of the Privacy Commissioner
Pharmaceutical Society of Australia
Physical Disability Council of NSW
Public Interest Advocacy Centre
Royal Australasian College of Physicians
Royal Australasian College of Surgeons
Royal Australian and New Zealand College of Ophthalmologists

Attendance at Melbourne Forum 29 July 2009
Allied Health Professions of Australia
Australian and New Zealand College of Anaesthetists
Australian Health Insurance Association
Australian Nursing Federation
Australian Privacy Foundation
Australian Psychological Society
Consumers Health Forum of Australia
Department of Prime Minister and Cabinet
Electronic Frontiers Australia
Health Services Commissioner (VIC)

Healthscope
Medical Indemnity Association of Australia
National Health & Medical Research Council
National Registration and Accreditation Implementation Project
Privacy Victoria
Royal Australasian College of Surgeons
Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Royal Australian College of General Practitioners
Speech Pathology Australia

Submissions by Organisations to Discussion Paper on Legislative Proposals July-August 2009 - where consent to these being made public has been received (available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/eHealth-submissions)

Australia and New Zealand College of Anaesthetists
Australian College of Health Informatics
Australian College of Nurse Practitioners
Australian Commission on Safety and Quality in Healthcare
Australian Democrats (ACT Division)
Australian Dental Association
Australian Health Insurance Association (AHIA)
Australian Medical Association
Australian Nursing Federation
Australian Physiotherapy Association
Australian Privacy Foundation
Bupa Australia
Cancer Council of Australia
Carers Australia
Civil Liberties Australia
Consumers Health Forum of Australia
Council of Ambulance Authorities
Crisis Support Services
CSC (Computer Sciences Corporation)
Department of Community and Safety Qld
Department of Innovation, Industry, Science and Research
Electronic Frontiers Australia
Giesecke & Devrient Australasia
Health Consumers Alliance of SA
Health Consumers' Council WA
Health Informatics Society of Australia
Health Information Management Association of Australia
Health Quality and Complaints Commission
Health Services Commissioner, Victoria
Inspire Foundation
Insurance Council of Australia
Law Council of Australia
Liberty Victoria
LifeSense
Medical Deans Australian and New Zealand Secretariat
Medical Indemnity Industry Association of Australia

Medical Practitioners Board of Victoria
National Cervical Screening Program
National Coalition of Public Pathology (NCOPP)
NSW and National Councils on Intellectuality Disability
Office of the Privacy Commissioner
Office of the Public Advocate - QLD
Office of the Victorian Privacy Commissioner
Officer of the Information Commissioner - QLD
Optometrists Association Australia
Pharmaceutical Society of Australia
Physical Disability Council of NSW (PDCN)
Privacy Committee of South Australia
Professional Services Review
Public Interest Advocacy Centre
Queensland Council for Civil Liberties
Queensland Health
Renal Health Networks WA
Royal Australasian College of Physicians
Royal Australian and New Zealand College of Ophthalmologists
Royal Childrens' Hospital
Services for Australian Rural and Remote Allied Health (SARRAH)
Standards Australia
The Council of Ambulance Authorities
The Australian Orthotic Prosthetic Association
The Australian Psychological Society
The Pharmaceutical Council of WA
The QLD Commission for Children and Young People and Child Guardian
The Royal College of Pathologists of Australasia
The Smith Family

B. Second consultation period with release of Exposure Draft legislation November 2009 – January 2010

November 2009 Pre-Consultation Meetings

Australian Medical Association
Australian Privacy Foundation
Cancer Voices Australia
Civil Liberties Australia
Consumers’ Health Forum
Cyberspace Law & Policy Centre, UNSW
Electronic Frontiers Australia
Federal Office of the Privacy Commissioner
Health Informatics Society of Australia
Liberty Victoria
Medical Software Industry Association
NCOSS (Council of Social Service of NSW)
Public Interest Advocacy Centre
Queensland Council of Civil Liberties

Stakeholder forum, Canberra – 20 November 2009
ACT Human Rights Commission
Aged Care Association Australia
Argus
Australian and New Zealand College of Anaesthetists (ANZCA)
Australian Association of Occupational Therapists
Australian Association of Pathology Practices
Australian Association of Practice Managers
Australian Association of Social Workers (AASW)
Australian Bureau of Statistics
Australian College of Nurse Practitioners
Australian Commission of Safety and Quality in Healthcare
Australian Dental Association
Australian Diabetes Educators Association
Australian Diagnostic Imaging Association
Australian General Practice Accreditation Limited (AGPAL)
Australian General Practice Network
Australian Health Insurance Association (AHIA)
Australian Healthcare & Hospitals Association (AHHA)
Australian Medical Council
Australian National University Medical School
Australian Nursing Federation
Australian Orthotic Prosthetic Association
Australian Physiotherapy Association
Australian Primary Healthcare Research Institute
Australian Privacy Foundation
Australian Private Hospitals Association
Bupa Australia Group
Cancer Council Australia
Cancer Voices Australia
Capital Hill Consulting
Carers Australia
Cerner
CHIK Services
Combined Pensioners and Superannuants Association of NSW (CPSA)
Consumers Health Forum of Australia
Corum
CRANA*plus*
CSC (Computer Sciences Corporation)
Department of Defence
Department of Families, Housing, Community Services and Indigenous Affairs
Department of Health and Ageing
Department of Health and Families, Northern Territory
Department of Health, Victoria
Department of Human Services
Department of Innovation, Industry, Science and Research
Department of the Prime Minister and Cabinet
Department of Veteran’s Affairs
Dialog Information Technology
Dietitians Association of Australia

Episoft
Genie Solutions
Health Information Management Association of Australia
Health Issues Centre
Healthlinks.Net
Heart Foundation
International Technology Specialists P/L
Inverness Medical Innovations Australia
iSOFT Australia
Kidney Health Australia
Law Council of Australia
Liberty Victoria
Medical Indemnity Industry Association of Australia
Medical Indemnity Industry Association of Australia
Medicare Australia
Medicines Australia
Mednic/Lifesense/Nova Medica
Microsoft Australia
Minfos
National Coalition of Public Pathology
National E-Health Transition Authority (NEHTA)
National Health & Medical Research Council
National Health Call Centre Network (NHCCN)
National Seniors Australia
Office of the Health Services Commissioner (Victoria)
Office of the Medical Board, Queensland
Office of the Privacy Commissioner
Optometrists Association Australia
Pen Computing
Pharmaceutical Society of Australia
Physical Disability Council of NSW
Professional Services Review
Pulse IT
Queensland Health
Queensland Health
Royal Australasian College of Physicians
Royal Australasian College of Surgeons
Royal Australian and New Zealand College of Ophthalmologists
Royal College of Nursing, Australia
Royal College of Pathologist of Australasia
Services for Rural and Remote Allied Health (SARRAH)
Smart Health
Standards Australia
Stat Health Systems
The Australian Psychological Society Limited
The Pharmacy Guild of Australia
Universities Australia
Zedmed

Submissions by Organisations to Exposure Draft Bill Consultation Dec 2009 – Jan 2010.
http://www.health.gov.au/internet/main/publishing.nsf/Content/eHealth-submissions2

Aged Care Industry IT Council (ACIITC)
Australasian College of Health Informatics
Australian Association Pathology Practices
Australian Bureau of Statistics
Australian Commission on Safety and Quality in Health Care (ACSQHC)
Australian Council of Social Services (COSS)
Australian Democrats ACT Division
Australian Dental Association
Australian Dental Association Victorian Branch
Australian Federation of AIDS Organisations'
Australian Health Insurance Association
Australian Institute of Health and Welfare (AIHW)
Australian Medical Association
Australian Nursing Federation
Australian Osteopathic Association
Australian Physiotherapy Association
Australian Privacy Foundation
Australian Private Hospitals Association
Bupa Australia Group
Civil Liberties Australia
Consumers Health Forum of Australia
Council of Ambulance Authorities
Department of Families, Housing, Community and Indigenous Affairs
Epworth HealthCare
Geoff Sims Consulting Pty Ltd
HBF
Health Consumers Council WA
Health Information Management Association of Australia
Health Insurance Restricted Membership Association of Australia (HIRMAA)
Health Quality and Complaints Commission
Hospital Contribution Fund of Australia Limited (HCF)
Insurance Council of Australia
iSOFT Group Limited
Law Council of Australia
Liberty Victoria
Medibank Private Limited
Medical Indemnity Industry Association of Australia
Melbourne Pathology
National Rural Health Alliance
NSW Physiotherapists Registration Board
Office of the Health Services Commissioner, VIC
Office of the Privacy Commissioner
Office of the Victorian Privacy Commissioner
Population Health Research Network
Public Interest Advocacy Centre
Royal Australian College of General Practitioners
South Australian Department of Health
The Australian Psychological Society Limited

Attachment 3

NEHTA RESPONSES TO PIA

- **Five recommendations believed not applicable**

1. Malleson's Recommendation 7.7.1: Commonwealth, State and Territory Governments should consider explaining what designs (if any) other than a voluntary opt-in model were considered as alternatives to the present universal IHI model, including an "opt out" model or a federated model, and the reason for rejecting those alternatives.

   NEHTA response: Not applicable. The Council of Australian Governments decided in late 2008 that the benefits of patient safety and efficiencies for healthcare providers would be best achieved by a universally issued individual healthcare identifier underpinned by a strong and effective legislative framework that includes governance arrangements, permitted uses and privacy safeguards.

2. Clayton Utz Recommendation 10: Searching to activate an IHI record will involve searches across unactivated IHI records whose data subjects have not consented to the creation or use of their personal information in the UHI Services. We recommend that to protect the privacy of individuals with non active IHIs and to ensure that the search process cannot be exploited to find any details on persons who have not consented to the activation of their IHI:

   - the UHI Services use a separate activation searching process from the regular searching of activated IHIs;
   - in the activation searching process only one unique matching IHI record can be retrieved and displayed to the searcher (not multiple possible "hits") - this will require the searcher to continue entering more information about the presenting individual until a unique match is found by the UHI Services, rather than return,for example, five search results having same name and date of birth and different addresses;
   - the identity of the searching individual be logged in the audit log of that one retrieved IHI record;
   - the system check whether the IHI record is activated after locating a unique match; and
   - activation search activity be monitored to detect and investigate any patterns of retrieved records not being activated.

   NEHTA response: No longer applicable. This recommendation relates to controls around deactivated IHI records. IHIs will now be universally issued, in line with the policy decision by the Council of Australian Governments. Refer to recommendation 3 [giving individuals a choice about activation and deactivation of their identifier. Our response to Rec 3: NEHTA has implemented government policy on allocation of identifiers. The Council of Australian Governments decided in late 2008 that the benefits of e-health would be best achieved by a universally issued individual healthcare identifier underpinned by a strong and effective legislative framework that includes governance arrangements, permitted uses and privacy safeguards. The design of the HI Service reflects this policy. Healthcare providers registered with one of the core medical associations will be allocated an HPI-I].

3. Clayton Utz Recommendation 11: NEHTA's design setting is that for unactivated IHI records where the individuals have not made a decision whether to activate their IHI records, the UHI Services will continue to collect individuals' personal information from Medicare Australia's databases and continually update those IHI records. This continual updating will occur without the consent of the individual concerned. We recommend that NEHTA consider further whether IHI records that have not been activated should be updated by taking into account the privacy considerations, operational practicality and the requirement for accurate search during an activation.

   NEHTA response: No longer applicable. This recommendation relates to controls around deactivated IHI records. IHIs will now be universally issued, in line with the policy decision by the Council of Australian Governments. Refer to recommendation 3.

4. Clayton Utz Recommendation 12: Use and disclosure of IHI records before activation (see also Recommendation 11) Because personal information held in IHI records that have not been activated is collected without the consent of the individuals concerned, we recommend that there should be strict prohibitions imposed by legislation on any collection use or disclosure of these IHI records other than in an activation process.

   NEHTA response: No longer applicable. This recommendation relates to controls around deactivated IHI records. IHIs will now be universally issued, in line with the policy decision by the Council of Australian Governments. Refer to recommendation 3.

5. Clayton Utz Recommendation 13: Opting out of the IHI Service – not activating or deactivating an IHI and its consequences

   NEHTA response: No longer applicable. This recommendation relates to controls around deactivated IHI records. IHIs will now be universally issued, in line with the policy decision by the Council of Australian Governments. Refer to recommendation 3.

- **Three recommendations NEHTA declined to support**

1. Malleson's Recommendation 7.8.4: In addition to, or as an alternative to Recommendation 7.8.3 consideration should be given to allowing Healthcare Provider Organisations to establish a single IHI for use by all individuals seeking anonymous healthcare at that organisation.

   NEHTA response: NEHTA does not support this recommendation. Using one IHI for multiple patients would compromise patient safety. A single IHI for many patients would remove the ability for a healthcare provider to separate different individuals in line with current practice. This would impair clinical decisions about an individual and lead to an increase in potential errors in diagnosis and treatment. In addition, the use of a 'generic' IHI for many individuals would remove potential future benefits for an individual who wishes to merge their records at some point in the future. Refer to response to recommendation 7.8.3 for the benefits of an alternative option for an individual to access anonymous healthcare, which is consistent with current practices for patients wishing to remain anonymous when receiving healthcare.

2. Malleson's Recommendation 7.11.1: Serious consideration should be given to removing the ability to batch search from the design of the HI Service, or limiting batch searching to existing, active patients.

   NEHTA response: NEHTA agrees that batch searching should be limited to existing patients. NEHTA does not support the recommendation to remove the ability for Healthcare Organisations to conduct batch searches. The batch request provides the same privacy safeguards as the individual search, but allows an authorised user within a Healthcare Organisation to perform the request in one transaction rather than in many transactions. A Healthcare Organisation can only obtain the IHI for its existing patients where they provide:

   a. Patient name and
   b. Patient date of birth and
   c. Either:
   d. Patient Medicare/DVA card number or
   e. Patient address and sex

   An authorised person within a Healthcare Organisation can conduct this search by entering these details for a patient. Where there is an exact match, the IHI will be returned.

3. Malleson's Recommendation 7.15.3: The audit log as made available to an individual should include the name or address of the Healthcare Provider Organisation that retrieved that individual's IHI from the HI Service. This will assist individuals in identifying which organisations have accessed their IHI and identifying unauthorised access.

   NEHTA response: NEHTA disagrees with providing the name or address of the HPI-I or HPI-O on the audit log as this will make the audit log a repository of sensitive information. Where an individual seeks further information about the detail of their audit log they will be able to contact the HI Service Operator for further response.

Healthcare Identifiers Service – Privacy Impact Assessments (PIA)

Three Privacy Impact Assessments (PIAs) have been undertaken in relation to the HI Service. A number of the recommendations made were referred by NEHTA to Governments for consideration. Outlined below is a summary of the recommendations referred and the action taken by Government to address the issues raised.

Mallesons Stephen Jacques PIA – completed mid 2009

Governance framework

Recommendation	How this recommendation has been addressed in the HI Bills
Recommendation 7.4.1: ***An appropriate privacy management framework should be established, including the following elements:*** *a)* ***robust, transparent and public mechanisms for the assessment of privacy impacts of each new use of the IHI*** *b)* ***robust, transparent and public mechanisms for the assessment of privacy impacts before any decision is made to widen the class of agencies and organisations that can directly or indirectly collect an IHI or other data from the HI Service*** *c)* ***robust, transparent and public mechanisms for the assessment of privacy and other impacts before any material change is made to Medicare Australia's systems and procedures affecting the HI Service*** *d)* ***robust, transparent and public mechanisms for the assessment of privacy and other impacts before any change is made to the form of participation agreement used in relation to the HI***	A framework for privacy management is provided for through the governance arrangements proposed in the Healthcare Identifiers (HI) Bills and the National Partnership Agreement for eHealth and includes: • oversight of the HI Service by the Ministerial Council (eg Health Ministers); • Medicare Australia as the Service Operator will only be able to undertake functions set out in legislation; • only authorised users will be able to access the HI Service and an audit trail each time someone accesses the Service will be maintained; • Medicare's current audit and complaints arrangements will continue to apply, with additional requirements specific to the HI Service; • Independent privacy and health regulators will have oversight of Medicare Australia's activities and healthcare organisations in line with current responsibilities; • Proposed changes that significantly depart from the intent of the legislation (eg use of HI Service outside the healthcare sector) would require consideration by the Ministerial Council and Federal Parliament; • Medicare Australia (in its capacity as HI Service Operator) will be

Service *e)* ***robust, transparent, public, well resourced and effective mechanisms for monitoring the collection, use and disclosure of IHIs or other data from the HI Service:*** - ***by Medicare Australia*** - ***in the provision of healthcare services, or*** - ***in any other field of endeavour, and*** f) ***robust, transparent, public and decisive action, promptly taken, to prevent and mitigate the effects of any inappropriate use of IHIs or other data from the HI Service.***	required provide regular reports to the Ministerial Council on the operation of the HI Service; and - Specific offences and penalties have been included to address any inappropriate handling of healthcare identifiers by the Service Operator and other individuals.
Recommendation 7.4.2: *The framework should not rely on rule making powers that are not robust, public and transparent.*	The legislation provides robust, public and transparent governance and regulatory arrangements – see response to 7.4.1
Recommendation 7.4.3: ***Consideration should be given to establishing a separate statutory authority as the HI authority which could sub-contract the issue of IHIs and the operation of the HI Service to Medicare Australia and supervise Medicare Australia's activities in its role as HI Service Operator.***	An appropriate level of independence and transparency will be provided for by establishing a role for the Federal Privacy Commissioner and Ministerial Council in overseeing the operation of the HI Service.
Recommendation 7.4.4: ***Consideration should be given to whether State and Territory instrumentalities wishing to use the IHI should be required to implement the same minimum governance standards discussed in Recommendation 7.4.1, and should be subject to requirements no less effective than the IPPs that govern Medicare Australia.***	Until uniform national privacy arrangements for health information are in place, healthcare identifiers will be supported by existing privacy arrangements and specific privacy protections contained in the Healthcare Identifiers Bill, including strict limits on the use and disclosure of healthcare identifiers. It is intended that the privacy protections included in the Healthcare Identifiers Bill will apply to all private and public sector bodies. This includes state and territory public sector bodies. Complaints relating to healthcare identifiers will be handled by the Federal Privacy Commissioner. Where a state or territory has existing privacy arrangements in place, including an appropriate regulator, that regulator will be responsible for handling complaints relating to healthcare identifiers which are made against public sector organisations. Each state or territory will need to pass complementary legislation to put the arrangements in place.

	State and territory legislative proposals will be subject to consideration by the Ministerial Council, in accordance with the NPA for eHealth. Until state and territory arrangements are in place, complaints against a state or territory public body will be handled by the Federal Privacy Commissioner (section 29(2), Healthcare Identifiers Bill 2010). The handling of any personal information associated with a healthcare identifier will continue to be subject to existing privacy arrangements under Commonwealth, state or territory law that apply to the body holding the information.
Recommendation 7.4.5:** **It is proposed that Privacy Act restrictions on use of identifiers (NPP 7 or UPP 10) should not restrict the use or disclosure of information that includes a health identifier for funding, management, planning, monitoring, improvement or evaluation of health services and for research purposes in the public interest subject to the same limits that apply to health information being used or disclosed for those purposes. If that proposal is implemented, a regulatory body (such as the HI authority if established pursuant to Recommendation 7.4.3) should monitor agencies and organisations relying on that provision. In accordance with those limitations on the use of health information, the collection and use should not take place if the relevant purposes are able to be effectively satisfied without collecting IHIs.	The legislative support for healthcare identifiers imposes specific limits on the adoption, use and disclosure of healthcare identifiers. Healthcare identifiers can only be used for health information management and communication as part of: • delivering a health service; • the management, funding, monitoring and evaluation of a health service; • research approved by a Health Research Ethics Committee; • the provision of indemnity cover for healthcare providers; • lessening or preventing a serious threat to an individual's life, health or safety or a serious threat to public health or public safety • establishing an authentication mechanism (such as a digital certificate) for a HPI-I and HPI-O; or • where it is otherwise authorised or required by law. **Healthcare identifiers are identifiers for the purpose of National Privacy Principle 7 and must not be adopted, used or disclosed by private sector bodies other than for the permitted purposes outlined above.**

Medicare Australia as HI Service operator

Recommendation	**How this recommendation has been addressed in the HI Bills**
Recommendation 7.5.1:** **For any change in a Medicare Australia policy that is used in relation to the HI Service, provision should be made for a PIA to be conducted to consider the impact of the change on	In accordance with the HI Bills and the National Partnership Agreement for eHealth, changes to policies relating to the operation of the HI Service will be considered by the Ministerial Council. Depending on the nature of the

individuals.	changes proposed, amendments to legislation may also be required. There is no intention to include a specific requirement to conduct a PIA for every change, as the need for this will depend on the type of change being considered. However, as is standard practice for Commonwealth agencies, the privacy impact of significant changes to the HI Service would be assessed, for example through a PIA, on an 'as required' basis.
Recommendation 7.5.3: *The enabling legislation for the HI Service should specify that NPP 7 and UPP 10 apply as though, in relation to IHIs, Medicare Australia has no functions other than its functions as the HI Service Operator.*	NPP 7 does not apply to Medicare Australia. However, under the HI Bills, Medicare Australia can only operate under the functions provided to it as the HI Service Operator. It can only use or disclosure information in relation to its HI functions as the HI Bill provides. It will also be subject to the Privacy Act in relation to personal information it holds for the HI Service functions. The IPPs will also continue to apply to Medicare Australia as a Commonwealth agency, in its role as Service Operator.

Potential for expansion of the HI Service

Recommendation	How this recommendation has been addressed in the HI Bills
***Recommendation 7.6.1:* The enabling legislation should clarify that the sole secondary use that may be made by Medicare Australia of data from the HI Service is in carrying out data quality maintenance and audits of IHI Datasets, subject to the approval of additional purposes through the process in Recommendation 7.4.1.**	In accordance with the HI Bills, healthcare identifiers can only be used for a limited number of purposes. Secondary uses of the information associated with the healthcare identifier will continue to be regulated in accordance with the requirements under the Privacy Act 1988.
***Recommendation 7.6.2:* The governance framework should include robust, transparent and public mechanisms for the assessment of privacy impacts of each material expansion of the HI Service, or use of the IHI or other data from the HI Service.**	See response to Rec 7.4.1

Anonymous healthcare services

Recommendation	How this recommendation has been addressed in the HI Bills
***Recommendation 7.8.7:* Commonwealth, State and Territory Governments should consider specific restrictions in the design of the HI Service that would prevent the use of Verified IHIs by Healthcare Provider Organisations being made a condition of State or Territory**	The HI Bills in no way impose an obligation on healthcare providers or provider organisations to use healthcare identifiers. The use of healthcare identifiers will not be required in order for individuals to claim a healthcare benefit and treatment will not be denied to an individual where a healthcare identifier is unavailable.

funding.	

Scope of Healthcare Providers

Recommendation	**How this recommendation has been addressed in the HI Bills**
Recommendation: 7.9.1: ***Any addition to the class of organisations that are able to access the HI Service and use IHIs should be determined through the framework discussed in Recommendation 7.4.1.***	Access to the HI Service for the purpose of obtaining an individual's healthcare identifier for inclusion in a healthcare provider's records or to find a healthcare provider's identifier and contact details (for example, to send a referral) will be limited to the following groups: • Identified individual healthcare providers, that is, those who have been assigned a HPI-I; and • Individuals authorised to access the HI Service on behalf of an identified healthcare provider organisation, that is, an authorised employee of an organisation that has been assigned a HPI-O. Regulations may prescribe requirements for assigning a healthcare identifier to a healthcare provider, such as eligibility criteria for healthcare providers and any security obligations that healthcare providers must meet. The addition of any other groups would require the consideration of the Ministerial Council.
Recommendation: 7.9.2: ***Consideration should be given to expressly preventing access to IHI Datasets, or collection or use of IHIs by organisations or government agencies for services and programs not directly related to healthcare.***	As outlined in the response to Rec 7.4.1, the use, adoption and disclosure of healthcare identifiers is limited to the purposes defined under the HI Bills and is intended to be used only within the healthcare sector. Any change to this requirement would require consideration by the Ministerial Council and involve a change to the legislation, ensuring appropriate Parliamentary scrutiny.

Access to the HI Service by Healthcare Providers

Recommendation	**How this recommendation has been addressed in the HI Bills**
Recommendation 7.10.1: ***Issues including those set out below should be addressed in the participation agreement with Healthcare Provider Organisations. Participation agreements should contain:*** ***a) defined rules of participation (eg minimum physical and logical***	As outlined in response to Rec 7.9.1, access to the HI Service will be limited to: • Identified individual healthcare providers, that is, those who have been

security, equipment and data management standards) ***b) defined rules in relation to access to the HI Service, and*** ***c) established consequences of breach of the participation agreement.***	assigned a HPI-I; and - Individuals authorised to access the HI Service on behalf of an identified healthcare provider organisation, that is, an authorised employee of an organisation that has been assigned a HPI-O. Regulations may prescribe requirements for assigning a healthcare identifier to a healthcare provider, such as eligibility criteria for healthcare providers and any security obligations that healthcare providers must meet.

Preventing unauthorised access to the HI Service

Recommendation	**How this recommendation has been addressed in the HI Bills**
Recommendation 7.13.1: ***Security breaches in relation to access to the HI Service should be subject to sanctions under the enabling legislation for the HI Service and those sanctions should be effectively enforced.***	Specific offences and penalties (including criminal penalties) have been included in the HI Bills to address inappropriate use and disclosure of healthcare identifiers by employees of the Service Operator and other individuals.

Specific limits on access by law enforcement agencies

Recommendation	**How this recommendation has been addressed in the HI Bills**
Recommendation 7.14.1: ***Consideration should be given to a specific legislative restriction on law enforcement and security agencies being generally able to access information held for the purposes of the HI Service.***	Current privacy laws permit law enforcement and security agencies to access information for certain purposes (such as to enforce criminal law). There is no general right of access to information by law enforcement and security agencies as requests for access need to be linked to a valid law enforcement or security purpose. Current proposals restrict adoption, use and disclosure of identifiers to the delivery of a health service, and that current authorised by law exceptions would continue to apply.

Audit log

Recommendation	**How this recommendation has been addressed in the HI Bills**
Recommendation 7.15.1: ***Legislation should clearly set out who may access the audit log and for what purposes. Any proposed uses of the audit log other than for the purpose of monitoring access to the HI***	The audit log in the HI Service will only be available to relevant staff of the HI Service Operator, to individual consumers and their authorised representatives. The HI Bills include an express right for individuals to access

Service should be subject to a PIA and community consultation.	information about themselves which is held by the Service Operator, including the audit log related to their healthcare identifier record.

Identity theft

Recommendation	How this recommendation has been addressed in the HI Bills
Recommendation 7.18.2: *NEHTA should consider the inclusion of a "breach reporting regime" either in the enabling legislation for the HI Service, or in the participation agreement between the HI Service Operator and Healthcare Provider Organisations.*	A specific data breach notification scheme has not been included in the HI Bills. Data breach notifications are due to be considered in the context of the Commonwealth response to the Australian Law Reform Commission's final report on Australian privacy laws.

Clayton Utz PIA – completed 2007

Recommendation	How this recommendation has been addressed in the HI Bills
Recommendation 1 – The regulation of the handling of UHI Services requires a new regime instead of the current patchwork of Australian privacy laws We **recommend** that there be new national privacy rules (possibly in the UHI Services enabling legislation) which cover, to the exclusion of existing privacy rules, the handling of UHI information provided to or by the UHI Services or derived from a IHI or HPI-I record. These new rules should: • be the same for the UHI Operator and all the UHI Services User organisations and downstream users (unless there are compelling reasons for different treatment); • not vary in their application according to whether UHI information might currently be characterised as health information or not because an organisation collected the UHI information in the course of providing a health service; • be developed by focussing first on what the policy should be as to the intended, permitted and prohibited collections, uses and disclosures of UHI information	The Healthcare Identifiers Bill establishes a national regulatory framework for the handling of healthcare identifiers. Each of the three dot points have been addressed as follows through the provisions in the Bill: • Specific requirements apply to the Service Operator and to the handling of identifiers within the wider healthcare community • Healthcare identifiers are regulated whether or not they would be categorised as 'health information' within a particular context • Permitted uses and disclosures for healthcare identifiers set out specific limits and rules for appropriate handling of healthcare identifiers and penalties apply to misuse

Recommendation	How this recommendation has been addressed in the HI Bills
without being constrained by current privacy law concepts of "health information", primary purpose and secondary purpose of collection of individual collectors and NPP 7-like identifier principles. These are inadequate mechanisms on their own to create the nuanced rule set needed for regulating the handling of UHI information, although they might be used as part of that rule set.	
Recommendation 2 – Primary purpose of collection of UHI information We **recommend** that a broad substantive purpose element needs to be added to NEHTA's current statement of Primary Purpose for it to serve as a useful umbrella for individual Primary Purposes of collection (acknowledging these will vary according to collecting organisation and context). We **recommend** the following formulations for consideration: It is intended that the particular Primary Purpose for any collection of an IHI and IHI record must fit within the umbrella purpose of accurate identification of an individual in order to provide healthcare services to that individual. It is intended that the particular Primary Purpose for any collection of an HPI-I or HPI-I record must fit within the umbrella purposes of accurate identification of a healthcare provider individual in order to: a) authenticate or authorise access to the UHI Services or health records or healthcare provider systems; or b) facilitate communications within the healthcare sector and with allied service providers; or c) accurately associate a healthcare provider with health information or any record of healthcare provision involving that provider. Communication with a healthcare individual is not within the proposed umbrella Primary Purpose for the IHI. Under current privacy law settings, use and disclosure of an IHI record to communicate with the individual for a particular purpose would be for a secondary purpose but in many cases would be permitted under the use and disclosure privacy principle. If certainty	The Bill clearly establishes the purpose in s3, and permitted uses and disclosures of healthcare identifiers are set out in s24.

Recommendation	How this recommendation has been addressed in the HI Bills
is required in relation to use and disclosure of personal information in the IHI record for communication purposes, we **recommend** that consent be obtained from individual healthcare consumers before such use and disclosure. Alternatively (or additionally), such use and disclosure may be authorised under legislation.	
Recommendation 14 – Function expansion We **recommend** that the legislative and governance underpinning of the UHI Services include a public and transparent statutory process to consider all proposals for any significant function expansion of the UHI Services (as to features, Users or uses of UHI data) to ensure that proposals for function expansion on the grounds of administrative convenience, efficiency and cost savings are balanced against the privacy impact of such proposals. The advice of an independent advisory board and public submissions should be taken before any authorised expansion of features, uses or Users is permitted.	Legislative and governance underpinnings for the HI Service are established in the Bill and in the National Partnership Agreement for E-Health agreed by COAG in December 2009.
Recommendation 15 – Controlling unintended uses and disclosures of UHI information We recommend that instead of relying on an identifier privacy principle like NPP 7, constraints on the adoption, use and disclosure of IHIs and HPI-Is and the associated records would be best achieved by: legislation, which: a) regulates the persons and purposes for which the IHIs and HPI-Is may be used within the healthcare sector and possibly allowing that such purposes may be expanded by obtaining the consent of the relevant individual; and b) prohibits the use of IHIs and HPI-Is outside the healthcare sector, which prohibition is (like NPP 7) not able to be overcome by obtaining the relevant individual's consent to wider user or	The Bill has been developed to regulate the persons who may use healthcare identifiers and the purposes for which identifiers may be used. Draft regulations (rather than participation agreements) set out the requirements for being assigned a healthcare provider identifier and the rules that healthcare providers will need to adhere to in relation to requests for healthcare identifiers from the HI Service.

Recommendation	**How this recommendation has been addressed in the HI Bills**
disclosures; terms in the relevant UHI Services participation agreements; or both (a) and (b).	
Recommendation 19 – Retention and destruction of UHI information We recommend that proposed uniform national rules regarding retention and destruction of UHI information including UHIs, UHI records and information obtained from UHI records be established (possibly in the enabling legislation for the UHI Services).	Under existing laws personal records must be retained for certain periods of time. As the healthcare identifier will be part of these records for example, in a patient's medical record, it is appropriate it is retained for the same period of time rather than imposing a separate requirement specific to healthcare identifiers. In accordance with the HI Bills, the Service Operator will be required to maintain a record of all healthcare identifiers assigned. It will be required to retain those for the period of time specified under Commonwealth archives legislation.

Galaxia PIA – 2006

Suggestions	How this recommendation has been addressed in the HI Bills
That the mandatory universal provision of an IHI with legislative backing would be the best model, rather than alternative consent and notice models such as "voluntary" or opt-in style options.	COAG have determined that the IHI will be universally issued – has been implemented by NEHTA and HI Bills provide the appropriate legislative support.
To manage community expectations about the national ID potential through IHI function creep, limits should be strengthened on the use of the IHI by prohibiting its use outside the health sector in specific legislation.	This issue has been addressed in the HI Bills – see response to Mallesons Stephen Jacques PIA – Rec 7.4.1 and 7.4.5
The full PIA will need to consider the legal restrictions on the adoption of a Commonwealth identifier by private sector organisations. The legal restriction may be waived by prescription in Commonwealth government regulations.	Subsequent PIAs considered this matter - see response to Mallesons Stephen Jacques PIA – Rec 7.4.5